

Exhibit H



DEA Trends & Update

Delaware Pharmacy Diversion Awareness Conference



March 19 & 20, 2016



The United States Department of Justice

Drug Enforcement Administration

Ruth A. Carter, Chief
Thomas W. Prevoznik, Chief
Liaison & Policy Section
Office of Diversion Control





Disclosure: Ruth A. Carter

I have no relevant personal/professional/financial relationship(s) to disclose



Goals and Objectives

- Public Health Epidemic
- Impact on Society
- Drugs of Abuse
- Criminal Activity
- The Controlled Substances Act: Checks & Balances
- Legal obligations: DEA registrant
- The DEA Response
- Miscellaneous Pharmacy Topics
- DEA Web-Based Resources



Public Health Epidemic





Laurel caretaker charged with medicine theft



robin brown, The News Journal

12:21 p.m. EDT October 28, 2015



53



3



53
CONNECT



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3
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MORE

A caretaker was charged with stealing medicines from a disabled woman in her 70s, police said Wednesday.

Ranada Pritchett, 34, of Millsboro, was arrested after police were notified of a medication theft from a home in Laurel, said Patrolman First Class Christopher Story, public information officer for the Laurel Police Department.

She was arrested after investigation determined she stole several prescriptions for Xanax and

Lorazepam, Story said.

In addition to taking the woman's prescribed tranquilizers from her home, he said, she also had the prescriptions refilled at an undisclosed drugstore

Pritchett later was released on \$4,000 unsecured bail.

Contact robin brown at (302) 324-2856 or rbrown@delawareonline.com. Find her on Facebook and follow her on Twitter @rbrowndelaware.

Camden nurse arrested on fraud charges

A Camden-area nurse, identified as Danielle M. Tharp-Strouse, 31, working at the Delaware Hospital for the Chronically Ill in Smyrna has been arrested on a number of fraud and forgery charges.



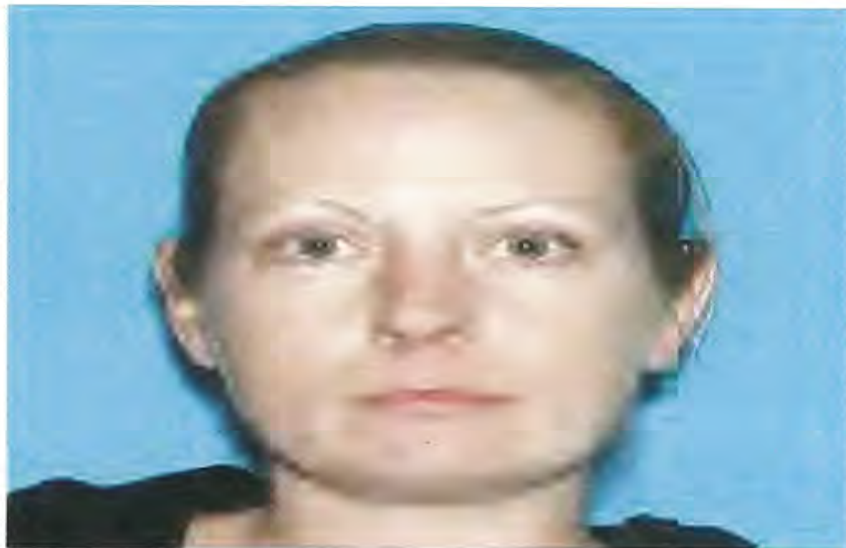
COMMENT

1



Tweet

0



Zoom

Delaware Department of Justice

Danielle M. Tharp-Strouse

By Staff reports

Posted Mar. 24, 2014 at 4:05 PM

Dover, Del.

A Camden-area nurse working at the Delaware Hospital for the Chronically Ill in Smyrna has been arrested on a number of fraud and forgery charges.

Danielle M. Tharp-Strouse, 31, of the 6100 block of Mud Mill Road, was taken into custody March 21 by members of the state Medicaid Fraud Unit, said Department of Justice spokesman Jason Miller.

The investigation began on March 19, 2013, when an administrator at the Smyrna health care facility reported to the Smyrna Police Department that an employee had been illegally obtaining Oxycodone, a powerful prescription painkiller, Miller said.

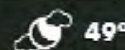
Smyrna Police turned the investigation over to the Medicaid Fraud Unit and its ongoing investigation found that between Feb. 1 and March 19, 2013, Tharp-Strouse allegedly forged the



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**BREAKING
NEWS**

Obama to announce Supreme Court pick today

Two Del. doctors tangled in Silk Road legal mess

Esteban Parra, The (Wilmington, Del.) News Journal 11:39 a.m. EST December 5, 2013

Investigators say pair teamed up to sell controlled substances on black market website.



WILMINGTON, Del. — Agents from the U.S. Drug Enforcement Administration say greed drove two Delaware doctors into a life of illegal drug sales on the black market Silk Road website.

(Photo: AP)

STORY HIGHLIGHTS

- Olivia Bolles is charged with illegal distribution of controlled substances on the Silk Road website

Olivia L. Bolles, 32, who recently completed her residency program at Christiana Care Health Center, is charged with illegal distribution of controlled substances including, Oxycodone, mixed amphetamine salts and Tetrahydrocannabinol or THC, the chemical responsible for marijuana's

MORE STORIES



Hockey goalie saves penalty by smashing through opposing player



NEWS



NEWS

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Delaware Pharmacist Gets 20 Years in Prison

Posted: Dec 20, 2012 1:25 PM EST

WILMINGTON, Del. (AP)- A former Claymont pharmacist who illegally distributed 45,000 Oxycodone pain pills was sentenced to 20 years in federal prison Thursday after tearfully asking his family and court officials for forgiveness.

Bruce E. Costa Jr., 37, wept as he described how greed, pride and arrogance led him down a destructive path of drug dealing, addiction and lying, and how his wife and three children have suffered.

"They're punished, and they don't deserve it, all because of my greed and my stupidity," the former owner of Renaissance Family Pharmacy told U.S. District Judge Leonard Stark.



(Photo: MGN)

ADVERTISEMENT



Public Health Epidemic

From 2000-2014 the rate of unintentional drug overdose deaths in the United States has increased **137%**, including a **200%** increase in overdose deaths involving opioids.

During this time period nearly half a million (500,000) people have died from drug overdoses.

In 2014, approximately **47,055** unintentional drug overdose deaths occurred--one death every 11.16 minutes.

There were approximately 1½ times more drug overdose deaths in the United States than deaths from motor vehicle accidents.

CDC National Center for Health Statistics/Morbidity and Mortality Weekly Report (MMWR); January 1, 2016



Public Health Epidemic

In 2014, **61% (28,647)** of these deaths involved some type of opioid, including heroin.

In 2014, CDC indicates that there were about ***19,000** “prescription opioid pain reliever deaths”.

Prescription drug abuse is the fastest growing drug problem in the United States.

**Historically, CDC has programmatically characterized all opioid pain reliever deaths (natural and semisynthetic opioids, methadone, and other synthetic opioids) as “prescription” opioid overdoses. In 2014, a sharp increase in deaths involving synthetic opioids (other than methadone) coincided with law enforcement reports of increased availability of illicitly manufactured fentanyl, a synthetic opioid. However, illicitly manufactured fentanyl cannot be distinguished from prescription fentanyl in death certificate data.*

CDC National Center for Health Statistics/Morbidity and Mortality Weekly Report (MMWR); January 1, 2016

*Email: Between CDC (Rudd) and DEA (Prevoznik) 2/18/2016

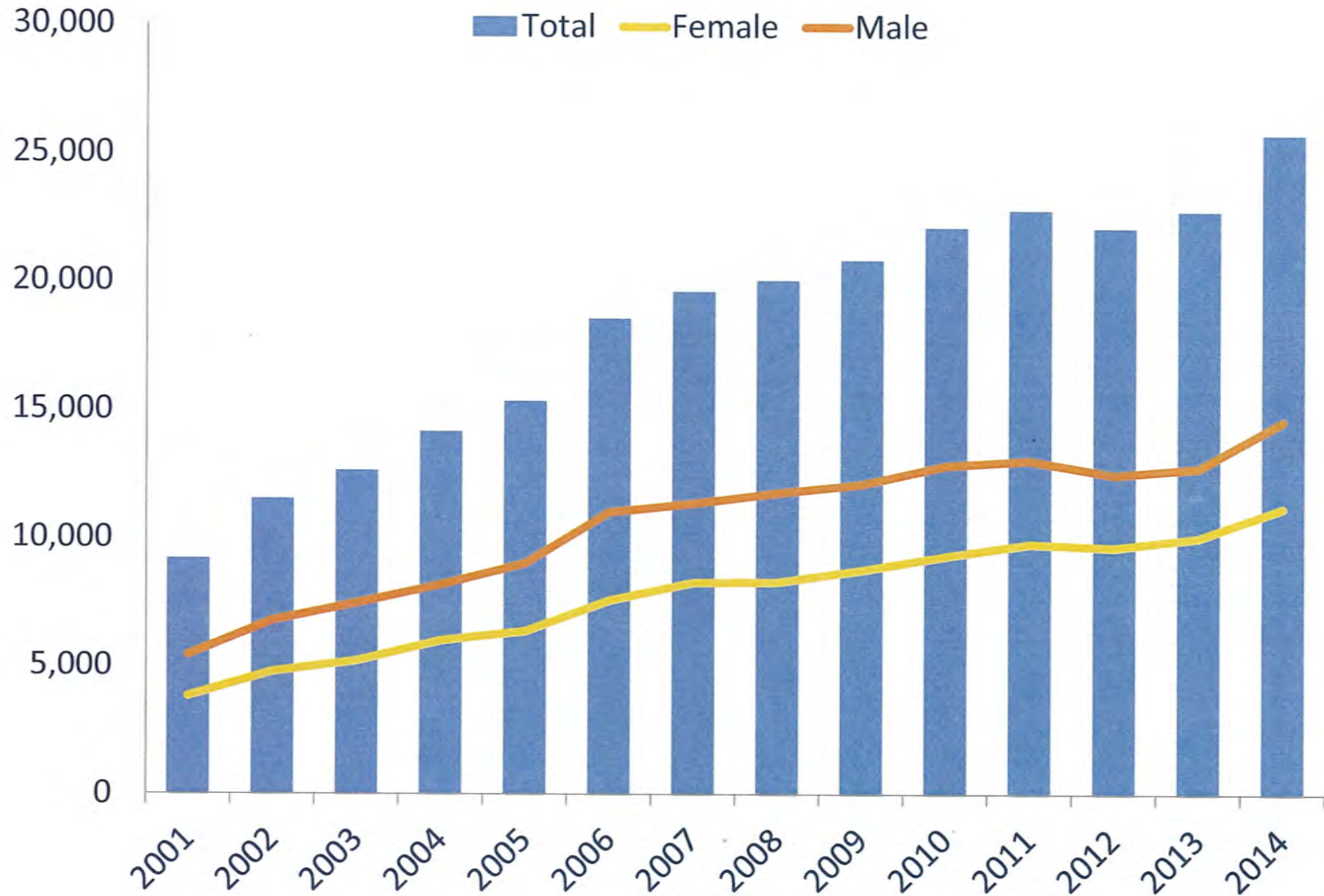


National Institute
on Drug Abuse



National Overdose Deaths

Number of Deaths from Prescription Drugs

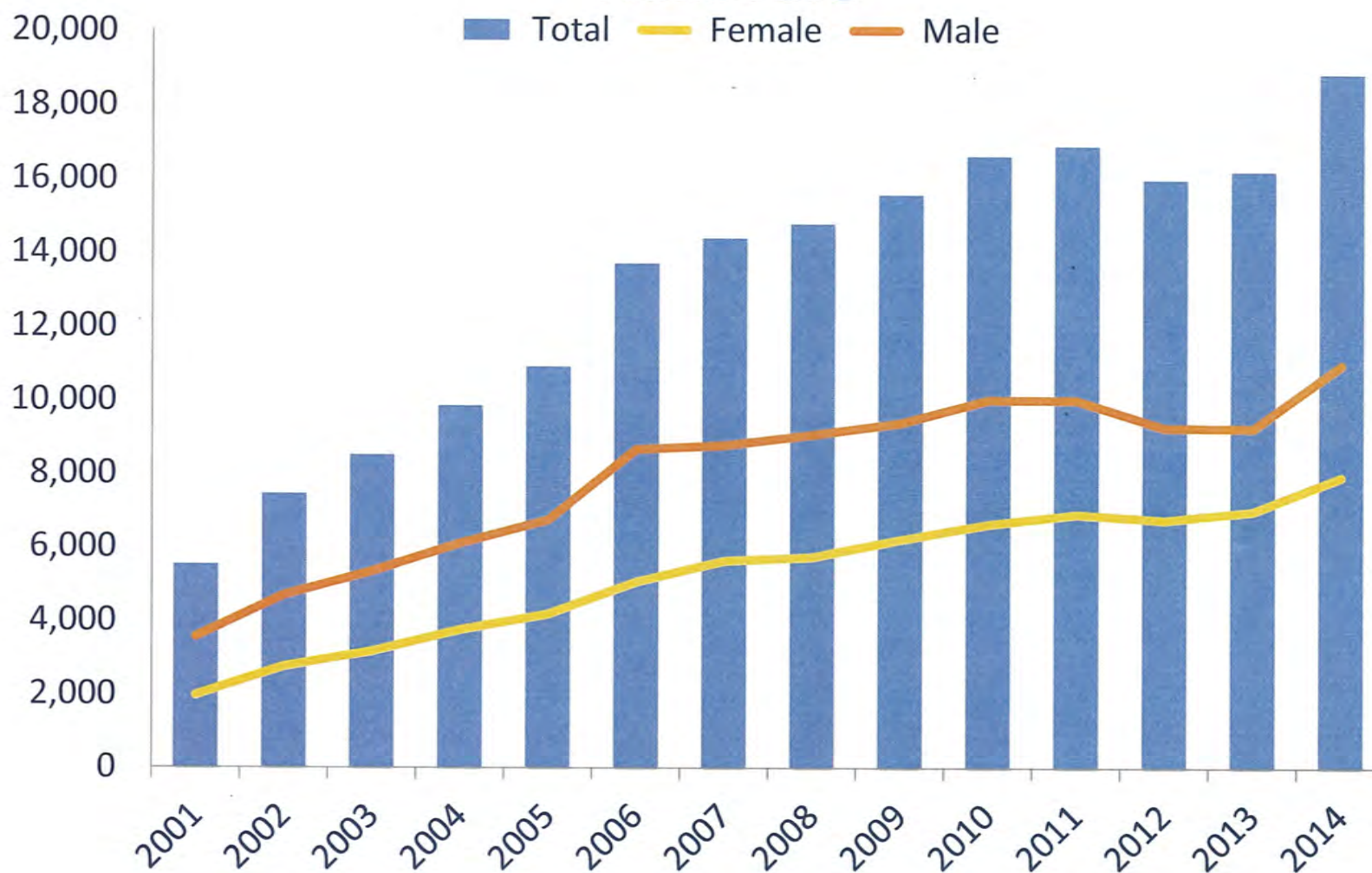


Source: National Center for Health Statistics, CDC Wonder



National Overdose Deaths

Number of Deaths from Prescription Opioid Pain Relievers



Source: National Center for Health Statistics, CDC Wonder

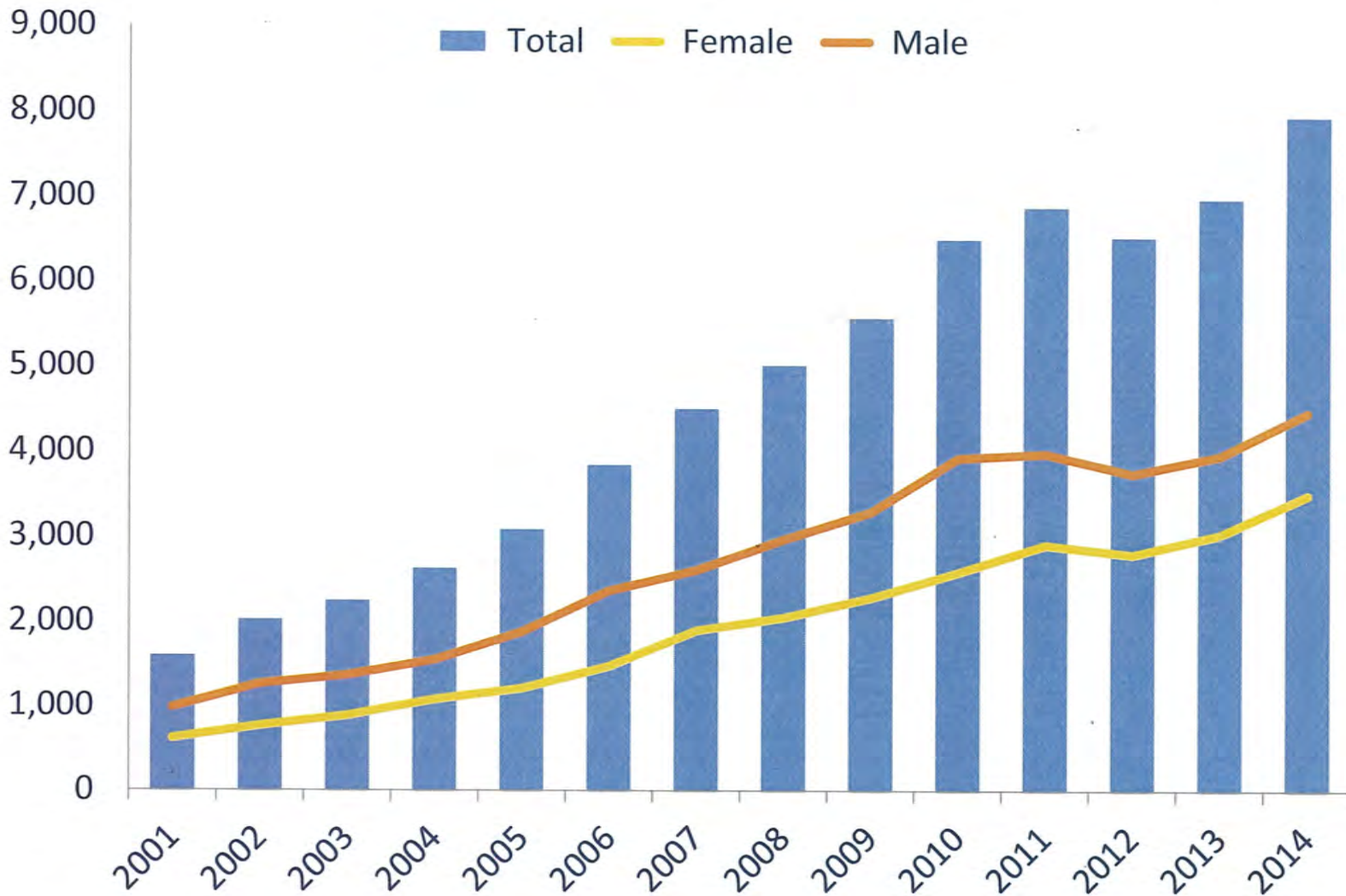


National Institute
on Drug Abuse



National Overdose Deaths

Number of Deaths from Benzodiazepines

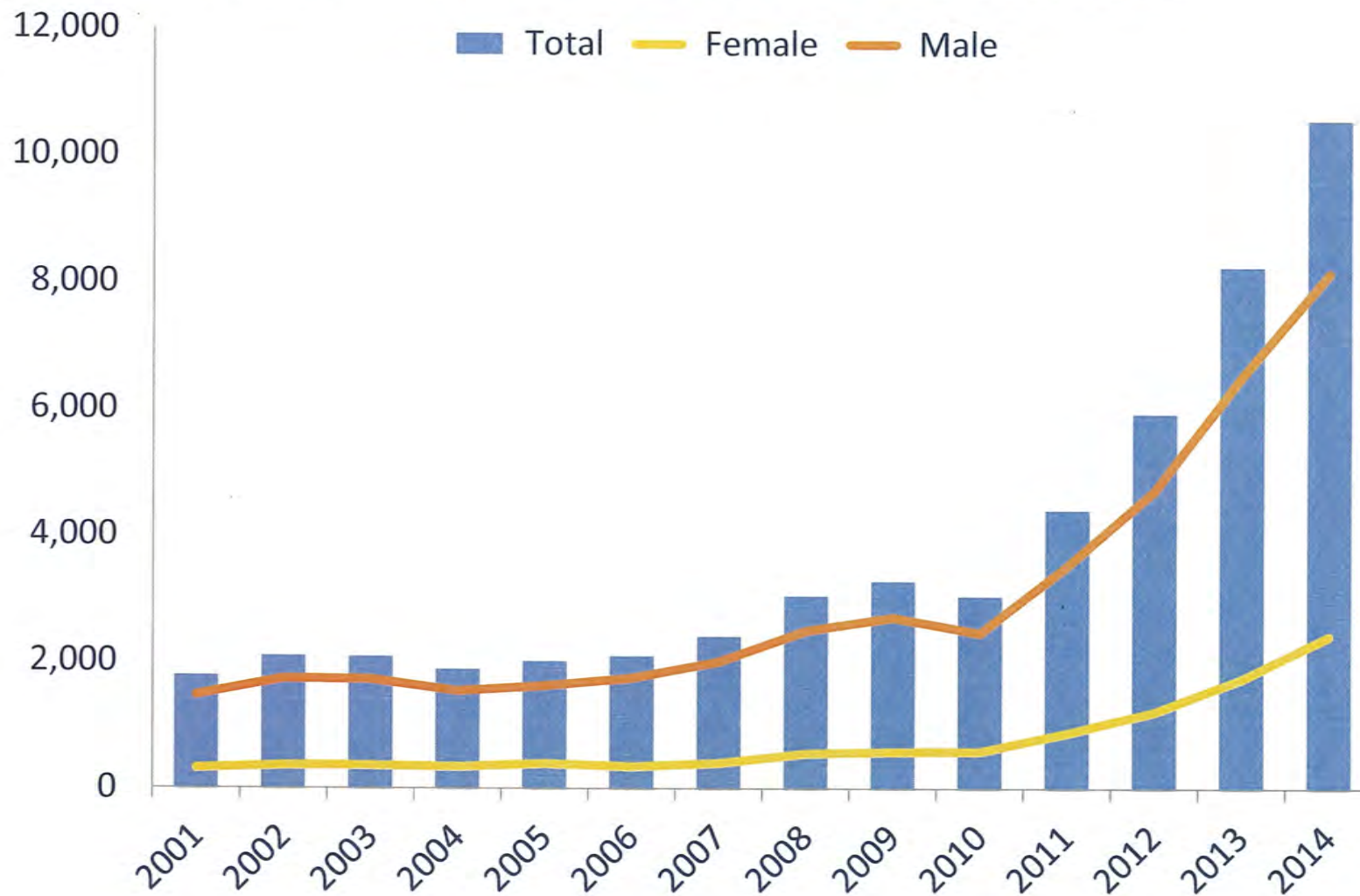


Source: National Center for Health Statistics, CDC Wonder

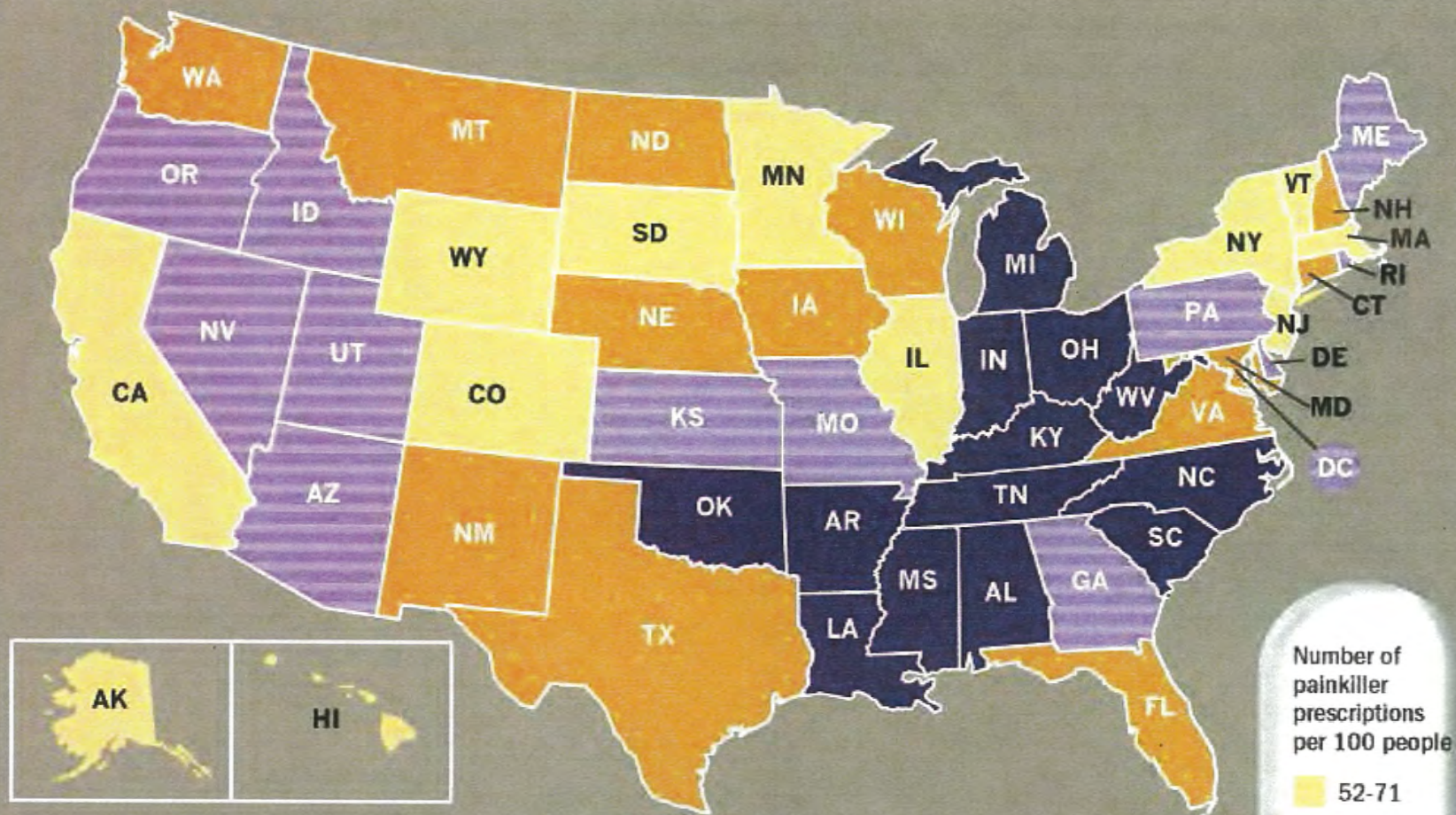


National Overdose Deaths

Number of Deaths from Heroin



Source: National Center for Health Statistics, CDC Wonder



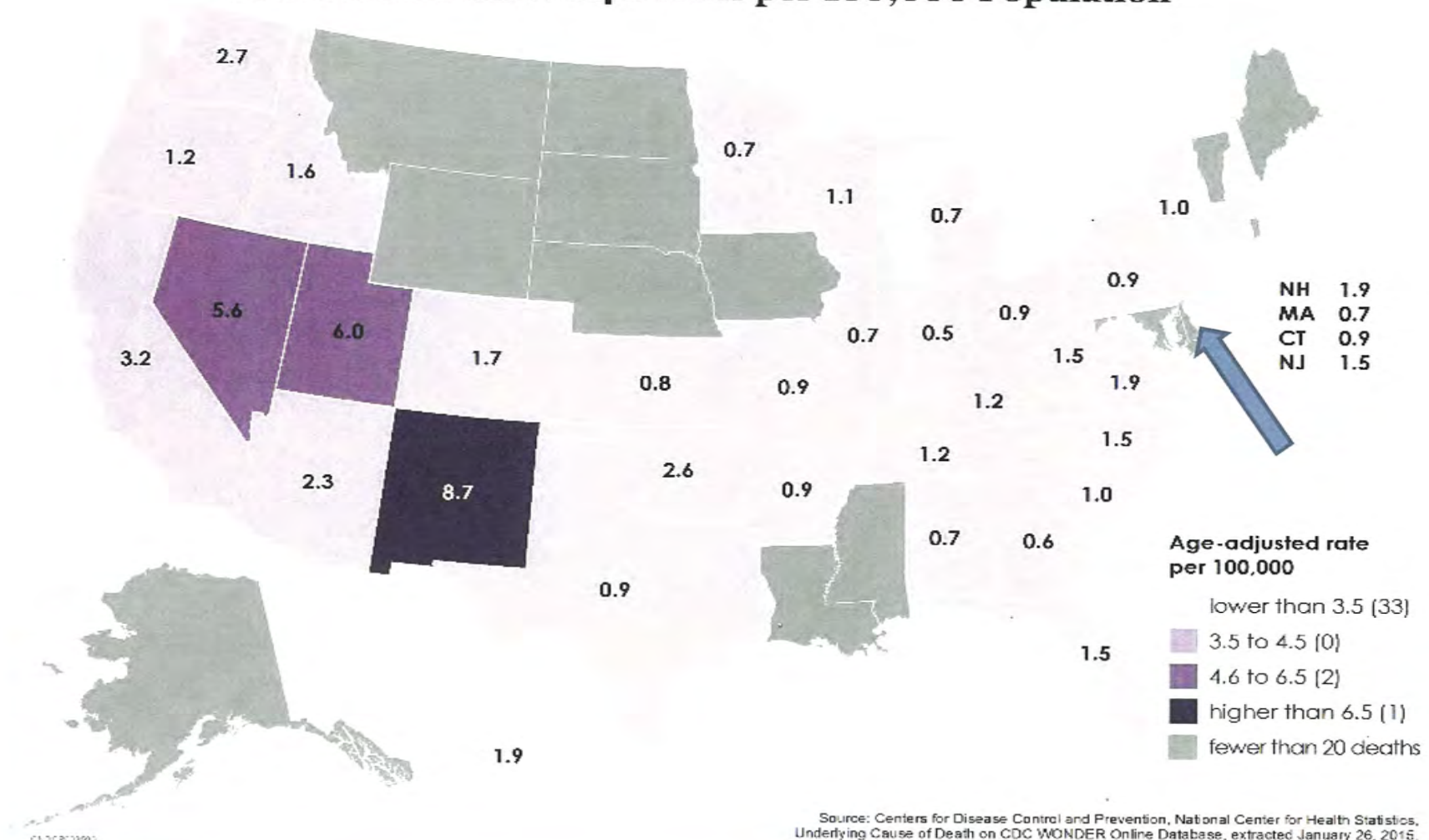
Some states have more painkiller prescriptions per person than others.

SOURCE: CDC Vital Signs, July 2014. cdc.gov/vitalsigns.

Prescription Opioid Analgesics Poisoning Deaths

Opioid-Involved Drug Poisoning Death Rates by State, 1999

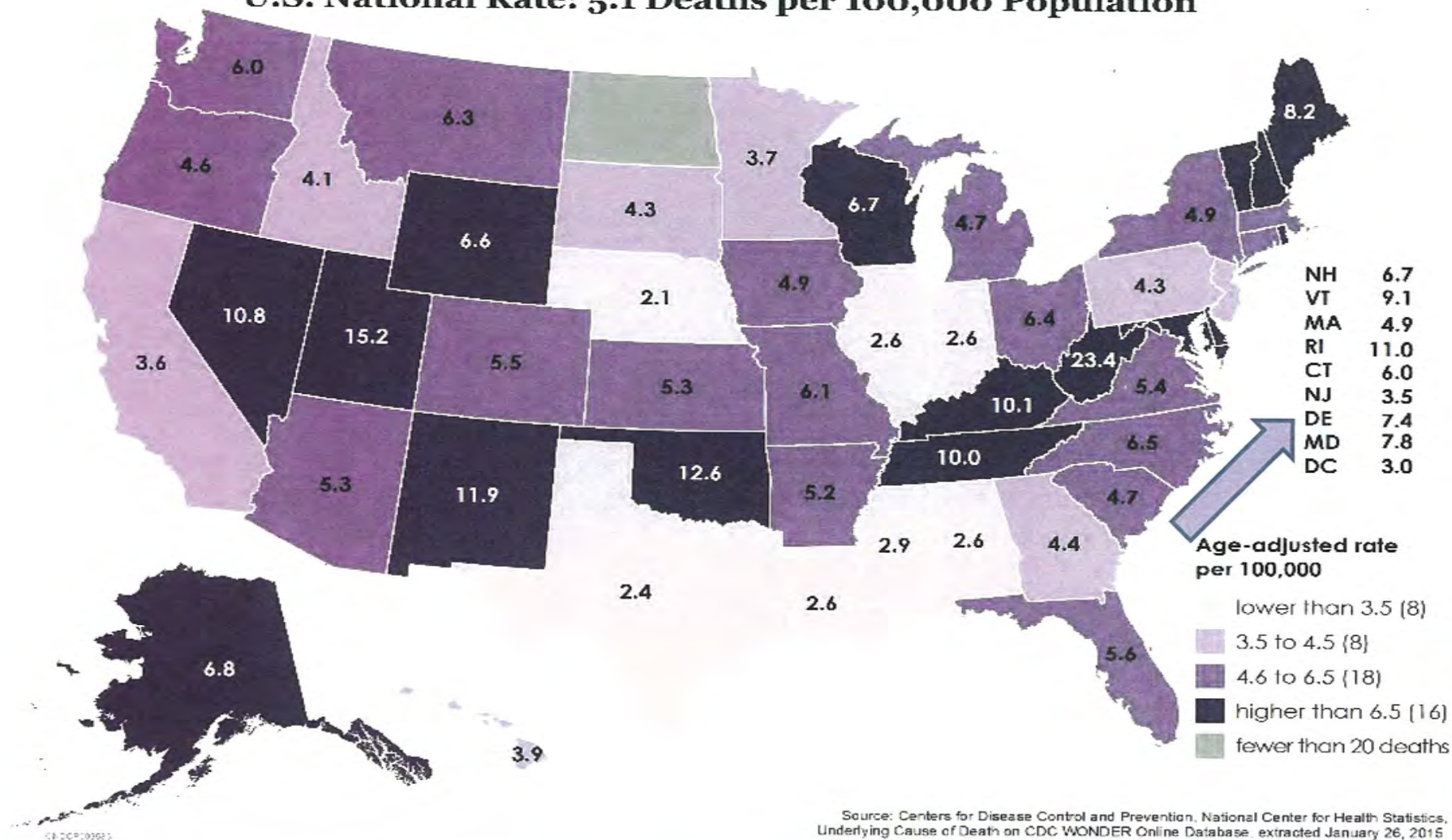
U.S. National Rate: 1.4 Deaths per 100,000 Population



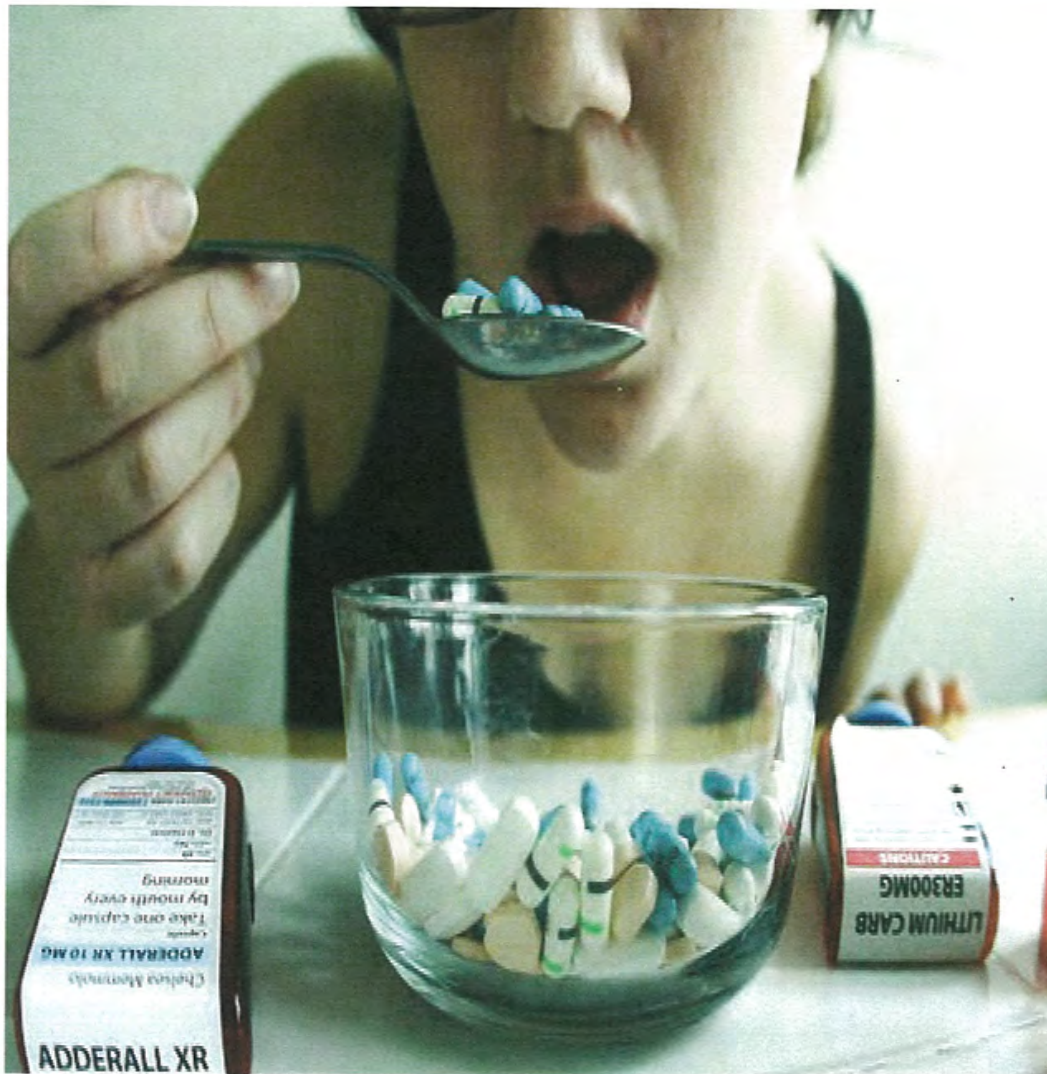
Prescription Opioid Analgesics Poisoning Deaths

Opioid-Involved Drug Poisoning Death Rates by State, 2013

U.S. National Rate: 5.1 Deaths per 100,000 Population



Our Youth



U.S. Drug Enforcement Administration
Office of Diversion Control



Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family...For Free!!



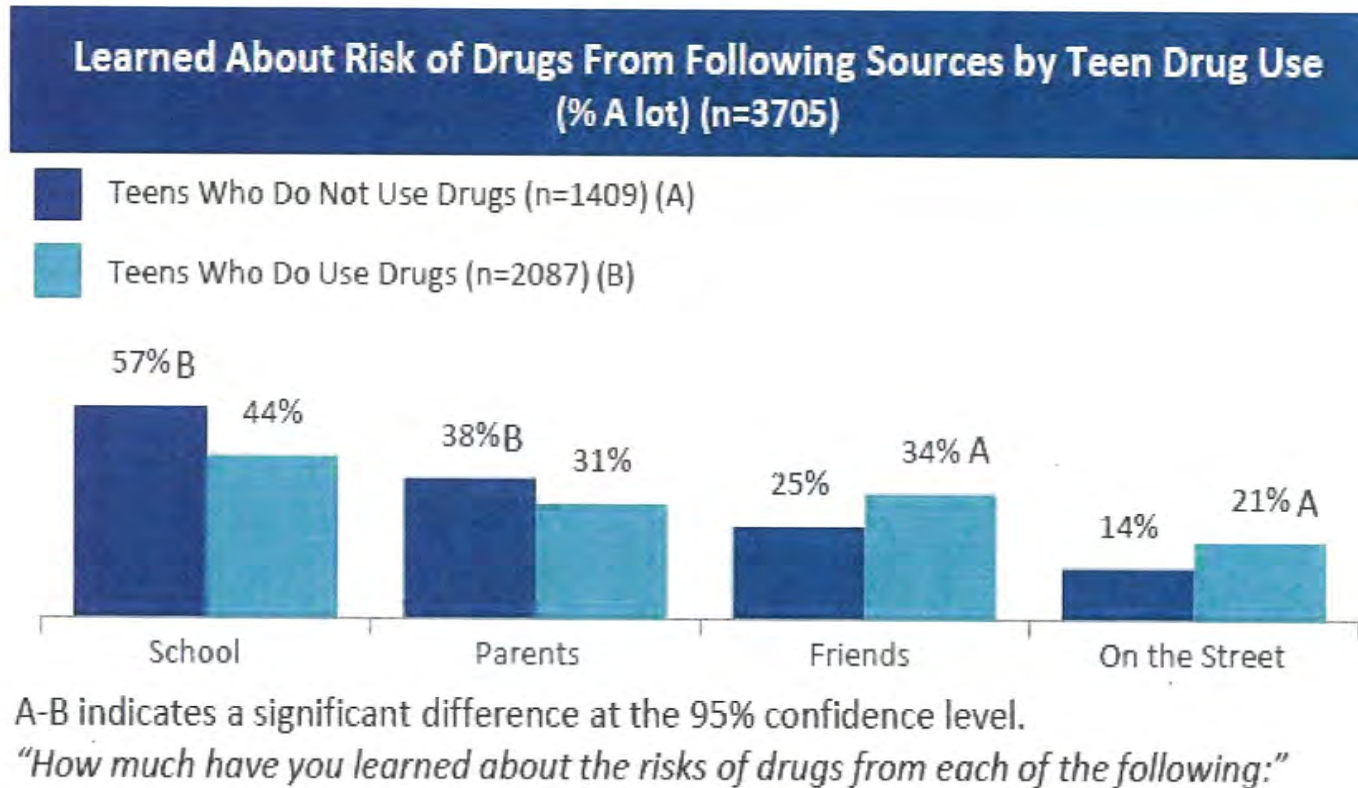


Medicine Cabinets: Easy Access

- More than half of teens (**73%**) indicate that it's easy to get prescription drugs from their parent's medicine cabinet
- Half of parents (**55%**) say anyone can access their medicine cabinet
- Almost four in 10 teens (**38%**) who have misused or abused a prescription drug obtained it from their parent's medicine cabinet



Where our kids learn about drugs!



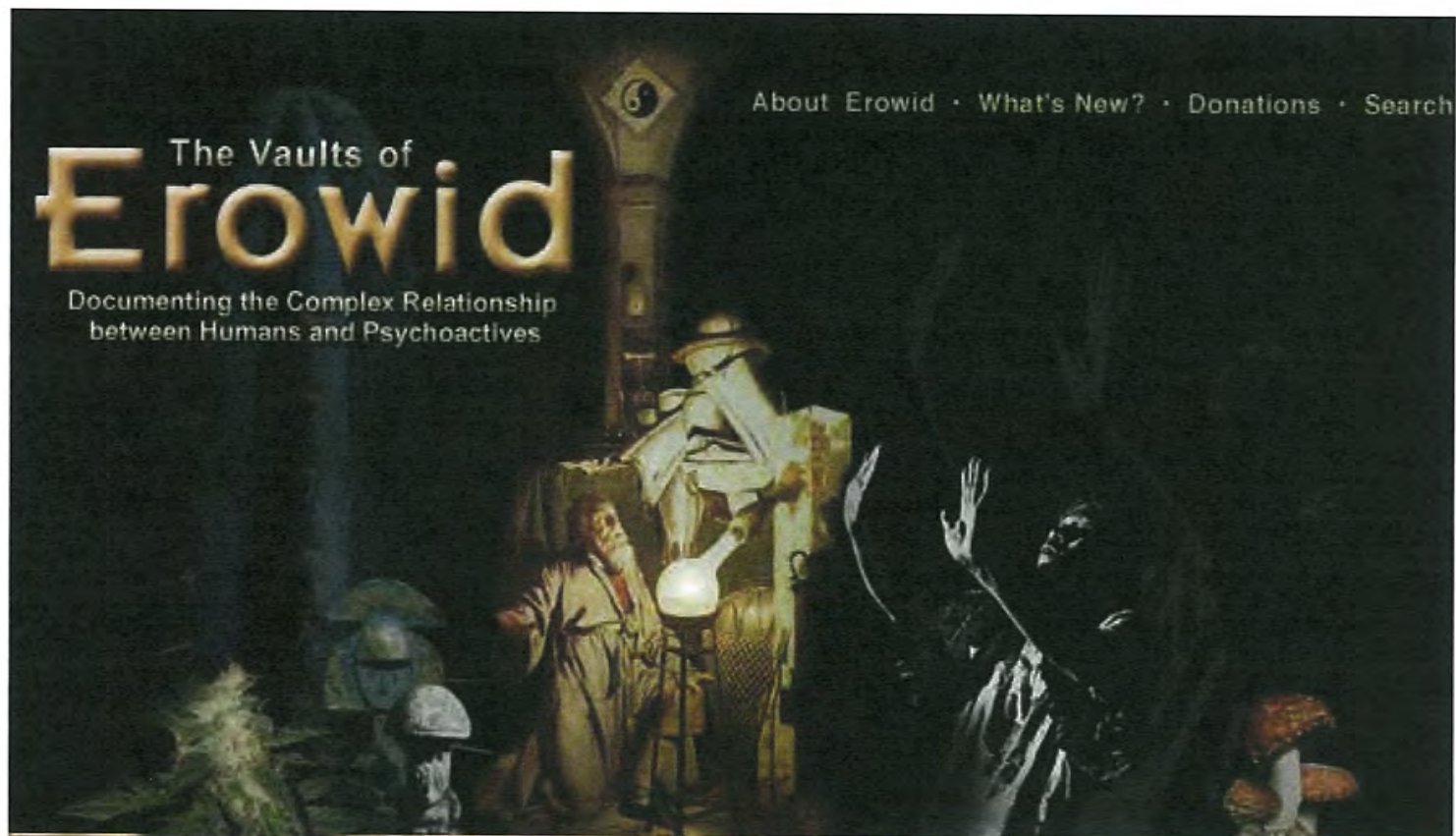
Partnership for Drug-Free Kids | The Partnership Attitude Tracking Study | Teens & Parents 2013

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14



Where else do our kids get their information from?

www.erowid.org



Where do kids get their information from?

www.bluelight.org

The screenshot shows the BlueLight website interface. At the top, there's a navigation bar with links for Home, Forum, What's New?, and Wiki. A search bar is also present. Below the navigation bar, a banner for the "HARM REDUCTION WORKSHOP with BLUELIGHT PSYCHEDELIC SCIENCE 2013" is displayed, dated April 10th in Oakland, California. The main content area features a "THE FRONT PAGE" section with a post by Sebastian Ghost (BL) dated 05-04-2013. The post discusses a major collaboration between BlueLight.ru and the Multidisciplinary Association for Psychedelic Studies (MAPS). The post includes an image of two hands shaking and text explaining that the MAPS forum will be migrating to BlueLight.ru. On the left side, there are sections for "Features" (including BlueLight Wiki, Blogs, BlueLight Mobile, Staff List, and Twitter) and "Forums" (listing various topics like Focus Forums, Drug FAQs, Ecstasy Discussion, Cannabis Discussion, Steroid Discussion, Psychedelic Drugs, Other Drugs, Drug Discussion, Drug Studies, Drugs in the Media, Basic Drug Discussion, and Advanced Drug).

← ↻ 🏠 📄 www.bluelight.ru/vb/

GoogleBlueLight

User Name Password Log in Help Register
☐ Remember Me?

BLUELIGHT

HARM REDUCTION WORKSHOP with **BLUELIGHT**
PSYCHEDELIC SCIENCE 2013 APRIL 10TH REGISTER NOW
OAKLAND MARRIOTT CITY CENTER • CALIFORNIA

Home Forum What's New? Wiki

The Front Page

If this is your first visit, be sure to check out the FAQ.
You may have to register before you can post: click the register link above to proceed. To start viewing messages, select the forum that you want to visit from the selection below.


Features

- BlueLight Wiki Our own Wiki project
- Blogs Blogs from our members
- BlueLight Mobile Use BlueLight on the go!
- Staff List Contact our staff members
- Twitter Follow us on Twitter

THE FRONT PAGE

A Letter to BlueLight and MAPS Forum members From Brad Burge (MAPS) and Sebastian Ghost (BL)

by Sebastian Ghost Published on 05-04-2013 06:57



It is with great pride and enthusiasm that we announce today a major collaboration between BlueLight.ru and the Multidisciplinary Association for Psychedelic Studies.

Through the efforts of Brad Burge, MAPS' Director of Communications, Rick Doblin, MAPS' Founder and Executive Director, Sebastian Ghost and The Love Bandit of BlueLight.ru, we will soon undertake an exciting partnership to reinvigorate the MAPS forum and increase opportunities for public education about psychedelic science and medicine. The existing plaintext email MAPS Forum will be migrating to BlueLight.ru, the world's leading drug information website. We're aiming to unveil the new MAPS Forums on BlueLight shortly before the Psychedelic Science 2013 symposium in mid-April.

In the coming weeks, the MAPS Forum will no longer be linked from maps.org. Instead, MAPS will provide a link to the new MAPS Forum hosted at BlueLight. MAPS will work closely with BlueLight to encourage public participation in our new "home" at BlueLight.ru as the migration of the MAPS Forum topics is completed.

...

start BlueLight - The Front ...



Violence





Armed Robbery

- Keep calm – Do as directed
- Do not challenge the bad actor – give him what he wants
- Let him leave the store without any intervention.
- As soon as he clears the store lock the door, call 911 and check on your customers/patients
- Write down any observations (clothing, height, weight, distinguishing features) while it is fresh in your mind
- Armed Robbery is usually an act of desperation. No amount of drug loss is worth your life or the life of your patients



Starting the year with a bang

Saranac Hale Spencer, The News Journal 12:36 a.m. EST January 4, 2016



(Photo: DELAWARE STATE
POLICE)

A 26-year-old Lewes man threatened to detonate explosives he said were strapped to his body if a pharmacist at a Walgreens near Magnolia didn't give him prescription drugs, according to state police.

The man, Curtis Kuhn, didn't actually have explosives strapped to his body, according to police.

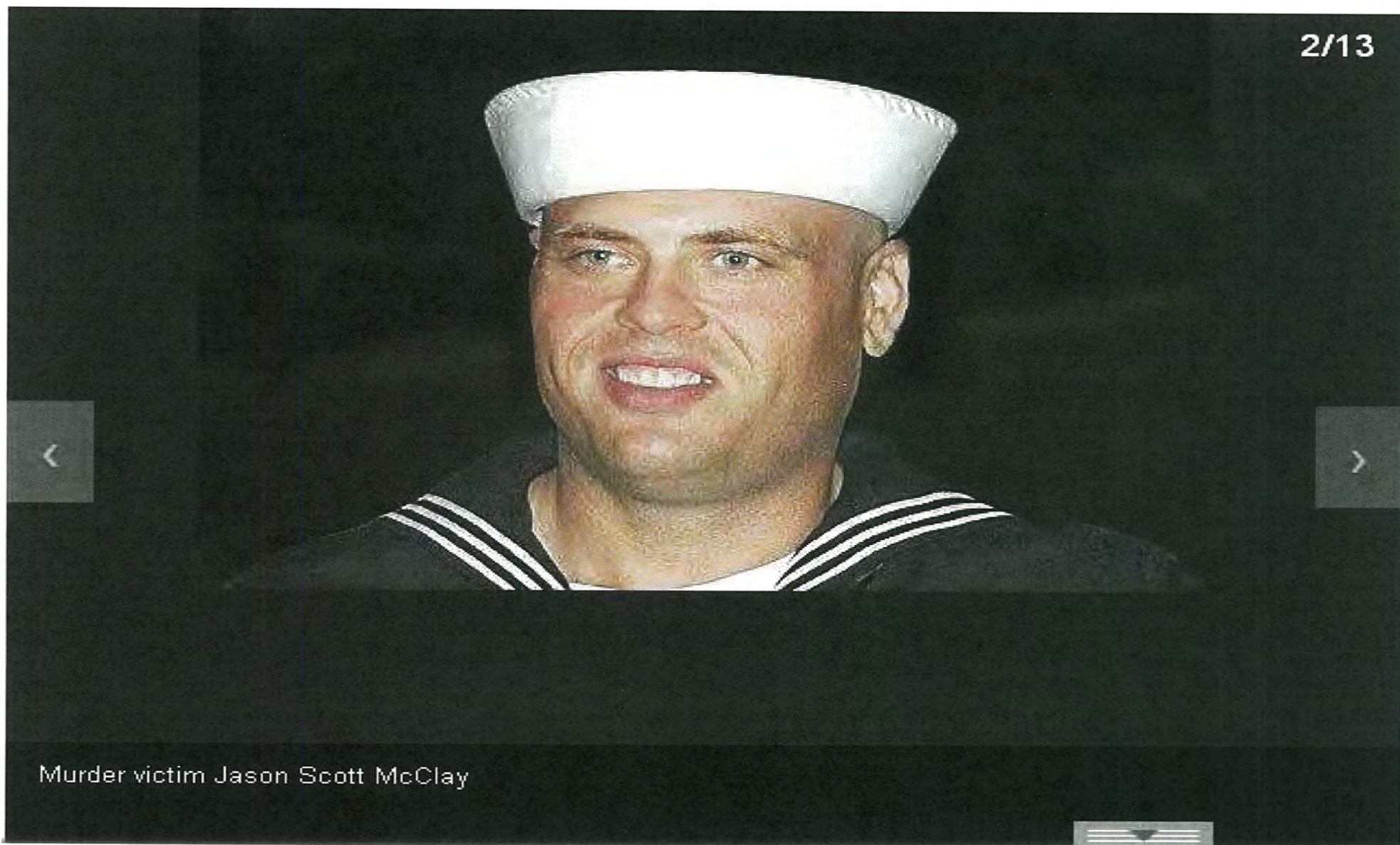
Kuhn went into the pharmacy at about 9:30 a.m. on Saturday and put a note on the counter demanding Percocet and Xanax – he told the pharmacist that he had explosives strapped to his body and he was being forced to commit the robbery by someone who was sitting in a car in the parking lot, according to police.

When officers arrived shortly after that, they took Kuhn into custody without incident and found that he had no explosives and there was no car fitting his description in the parking lot, according to police.

Kuhn was charged with first-degree attempted robbery, attempted theft of a controlled substance and two counts of terroristic threatening. He was arraigned and sent to Vaughn Correctional Center near Smyrna for lack of \$27,000 secured bond and

Fatal Links: Investigators put together puzzle to solve Rite Aid manager's murder

2/13



Murder victim Jason Scott McClay



Drugs of Abuse





Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen



INTERNATIONAL NARCOTICS CONTROL BOARD



Narcotic Drugs
Stupéfiants
Estupefacientes
2014

Estimated World Requirements for 2015
Statistics for 2013

Évaluations des besoins du monde pour 2015
Statistiques pour 2013

Previsiones de las necesidades mundiales para 2015
Estadísticas de 2013



UNITED NATIONS

- INCB Annual Report
Narcotic Drugs
- Estimated World
Requirements for
2015
- Statistics for 2013

U.S. Drug Enforcement Administration
Office of Diversion Control

**International Narcotics Control Board:
Comments on Reported Statistics on Narcotic Drugs**

The United States was the country with the highest
consumption of the following drugs:

2013	DRUG	2012
99%	Hydrocodone	99%
78%	Oxycodone	82%
57%	Morphine	57%
51%	Hydromorphone	42%
51%	Methadone	49%
31.5%	Fentanyl	37%

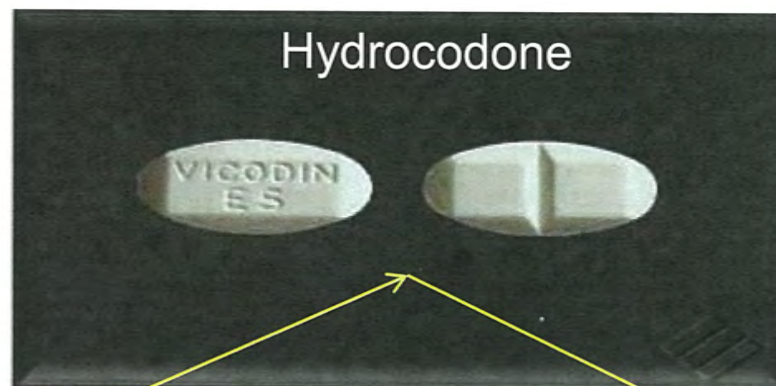
Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)
- Similarities:
 - Structurally related to codeine
 - Equal to morphine in producing opiate-like effects
- Brand Names: Vicodin[®], Lortab[®], Lorcet[®]
- Currently, combination products are Schedule III
- **October 6, 2014 moved to SCHEDULE II**
- “Cocktail” or “Trinity”
 - Hydrocodone
 - Soma [®] / carisoprodol
 - Alprazolam / Xanax[®]

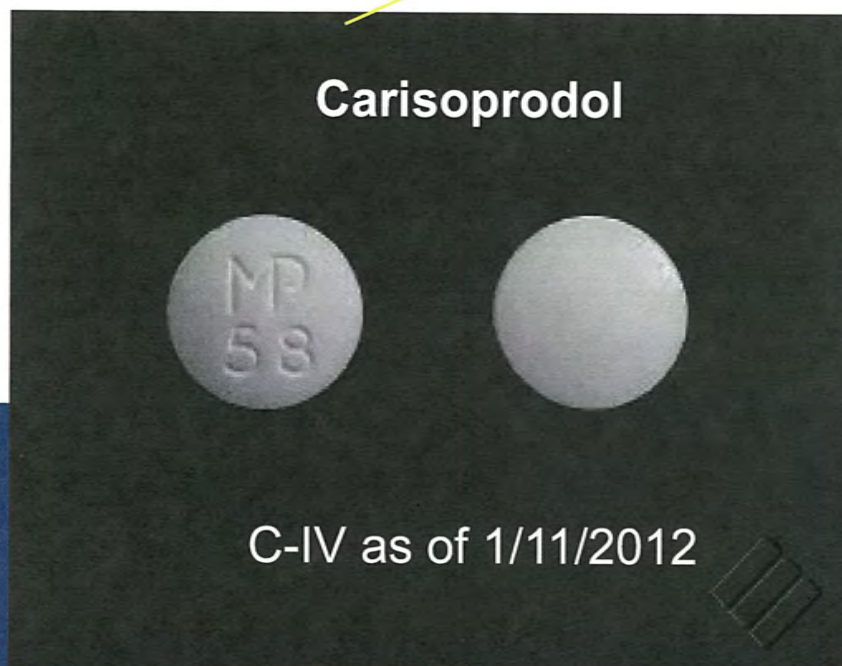


Street prices: \$2 to \$10+ per tablet depending on strength & region

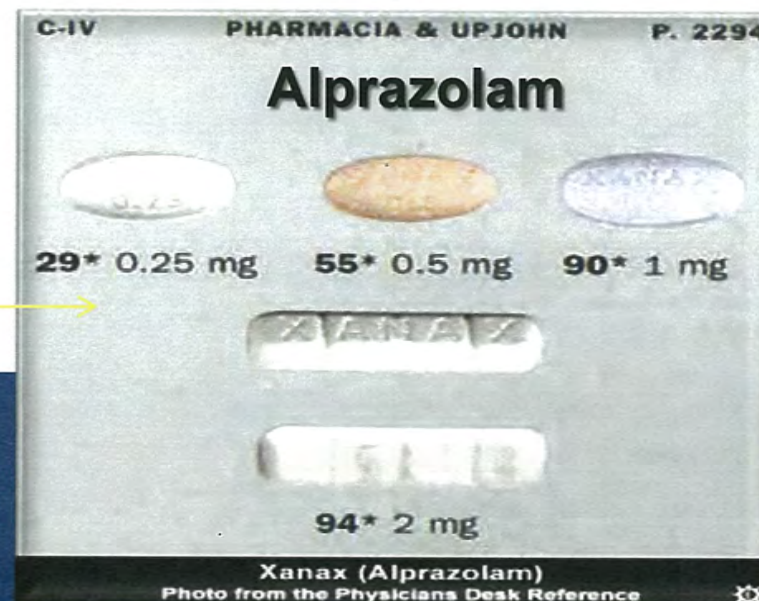
The Trinity



Opiate



Muscle Relaxant



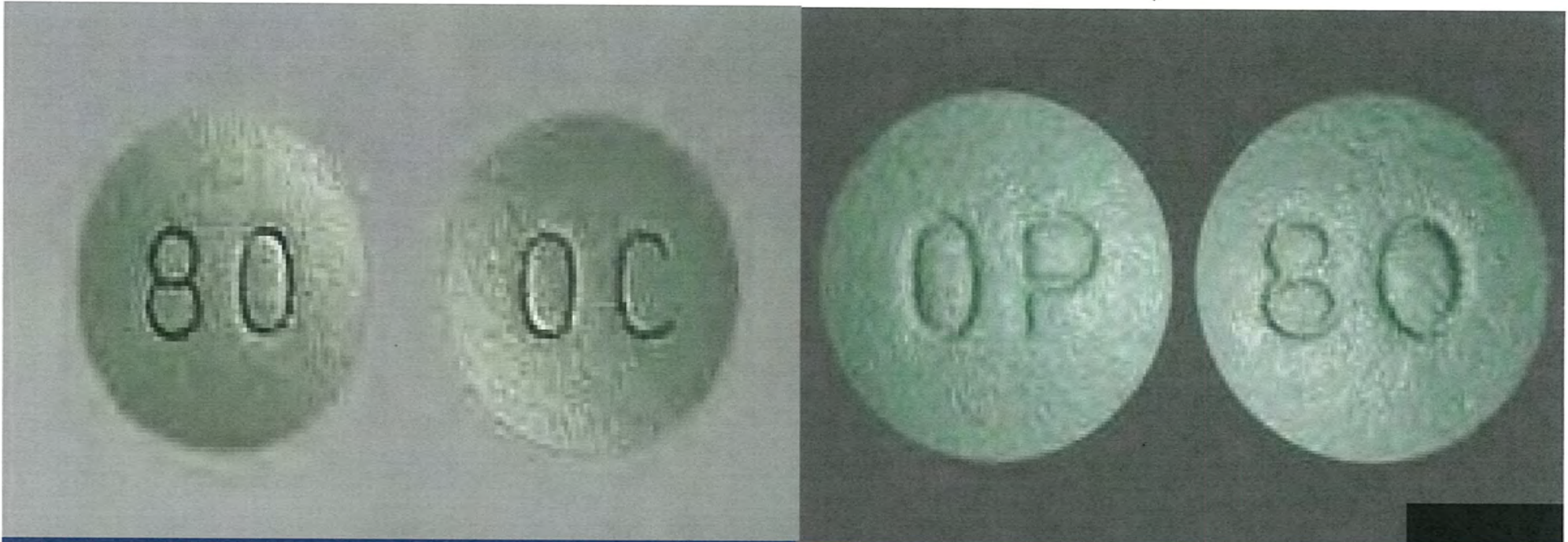
Benzodiazepine

Oxycodone

- OxyContin controlled release formulation of Schedule II oxycodone
 - The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
 - Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
 - 10, 15, 20, 30, 40, 60, 80mg available
- Effects:
 - Similar to morphine in effects and potential for abuse/dependence
 - Sold in “Cocktails” or the “Holy Trinity”
 - Oxycodone, Soma ® / Xanax®
- Street price: Approx. \$80 per 80mg tablet

NOTE: New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.



Oxycodone HCL CR (OxyContin®) Reformulation





New OxyContin® OP



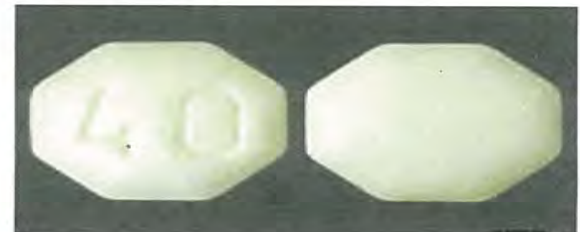
<p>08-27-2010, 01:11 AM</p> <p>mz.mary420 Member</p>  <p>Join Date: May 2010 Location: down south Posts: 6</p>	<p>#17</p> <p>well just got ours and they suck! when snorted the pill balls up in your nose and gets stuck, so i tried sucking on one and it did ok, but tastes nasty. No way you can shoot them as metioned in a previous post. havent tried smoking it yet, kinda in a hole money wise, it cost me over \$700.00 to get my 80s filled and i probably wont even get half my money back 😞</p> <p>* if anyone has tried to smoke this new formulated shit, please post! thanks</p> <p>Quote</p>
<p>08-27-2010, 06:09 AM</p> <p>mephist00 Member</p>  <p>Join Date: Apr 2008 Location: NY Age: 25 Posts: 628</p>	<p>#18</p> <p>ya my friend has tried to smoke the new ones... said its very harsh on the lungs and throat..</p> <p>so far the only way ive been able to beat the time release, is use a hose clamp to grind it very fine, and snort it.. it doesnt gel up like you would think (doesnt gel up like the football shaped generic 40's do anyways) it just kinda turns snotty.. but if you can get it down fast it seems to work ok</p> <p>Quote:</p> <p>Originally Posted by stalk <i>I've come to the conclusion it's because these psychedelic visions are simply vibrating on a higher, or different, spectrum of frequencies that normally the monkey does not perceive.</i></p>



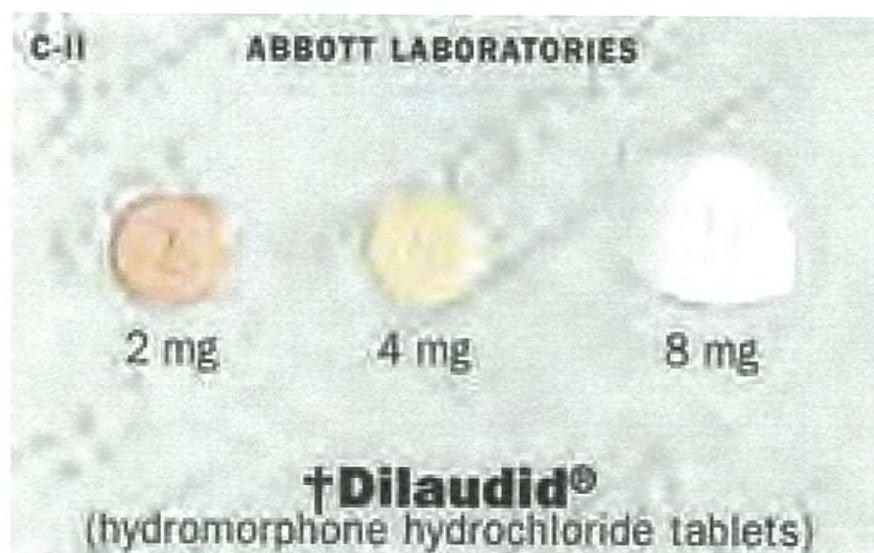
Oxymorphone Extended Release Opana ER® (Schedule II)

➤ Opana ER® - (Schedule II)

- Treats constant, around the clock, moderate to severe pain
- Becoming popular and is abused in similar fashion to oxycodone ; August 2010 (Los Angeles FD TDS)
- Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
- Street: \$10.00 – \$80.00



Hydromorphone



Other Opiates of Interest



Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 100 mg



Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 15 mg



Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 30 mg



Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 30 mg



Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 100 mg



Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 60 mg



Trade Name: Dilaudid
Controlled Ingredient:
hydromorphone hydrochloride, 1 mg

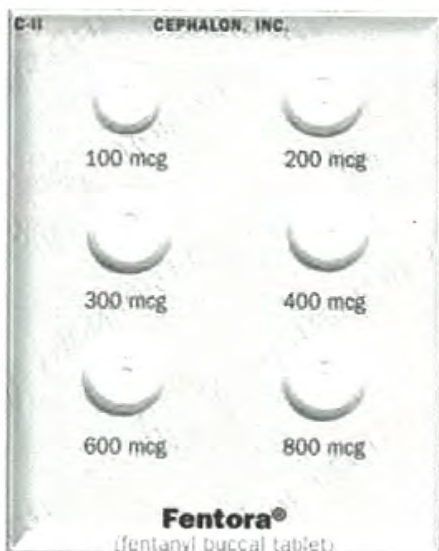


Trade Name: Dilaudid
Controlled Ingredient:
hydromorphone hydrochloride, 4 mg



Fentanyl

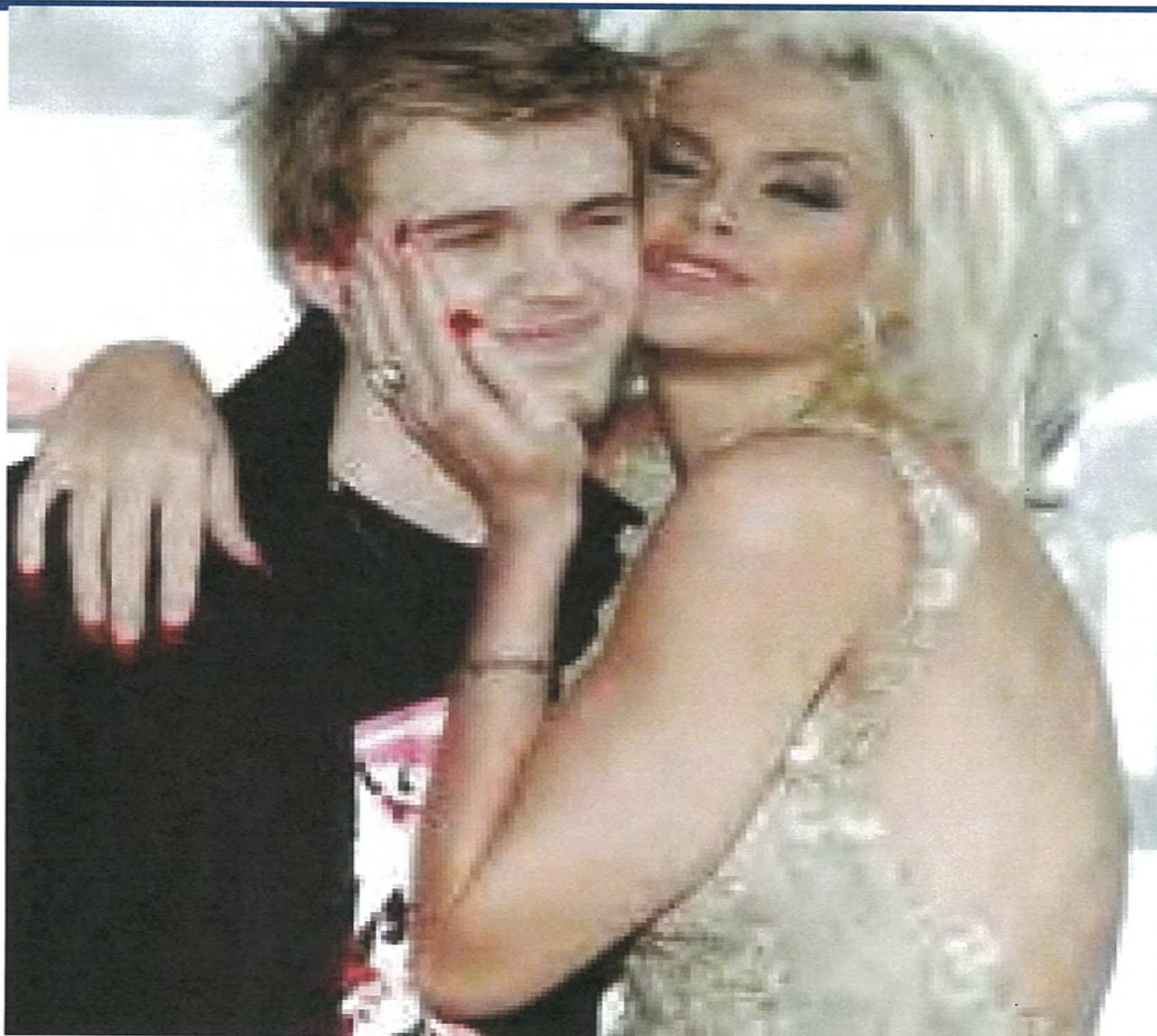
- Fentanyl Patches
- Fentanyl Citrate dispensed in a berry flavored lollipop-type unit
- Fentanyl is 100 times more potent than morphine
- Intended to be used for chronic cancer pain & only for people who are tolerant to prescription opioid (narcotic) pain medicines
- Abused for its intense euphoric effects



Fentora®



METHADONE



Methadone- 5mg & 10mg



Methadone 40 mg



NDC 0406-0540-34 100 TABLETS

METHADOSE™
Dispersible Tablets **CII**
(Methadone Hydrochloride
Tablets for Oral Suspension USP)

40 mg

Each tablet contains:
Methadone Hydrochloride USP, 40 mg
Rx only

Mallinckrodt

COVIDIEN™

Usual Dosage:
See accompanying literature for dosage.

Keep tightly closed.

Dispense in a tight container (USP) with a child-resistant closure.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Do not accept if seal over bottle opening is broken or missing.

Mallinckrodt Inc.,
Hazelwood, MO 63042 USA.

3 0406-0540-34 7



Treatment of Narcotic Addiction



WHY IS IT ALSO USED AS AN ANALGESIC?

Cheapest narcotic pain reliever – synthetic

Insurance companies

What's the problem?

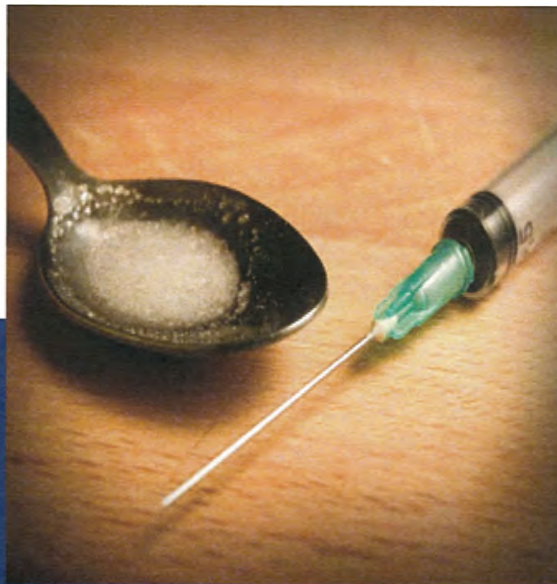


Overdose...Why?

- Patients not taking the drug as directed
- Physicians not properly prescribing the drug
- Non medical users ingesting with other substances
- Opiate naive

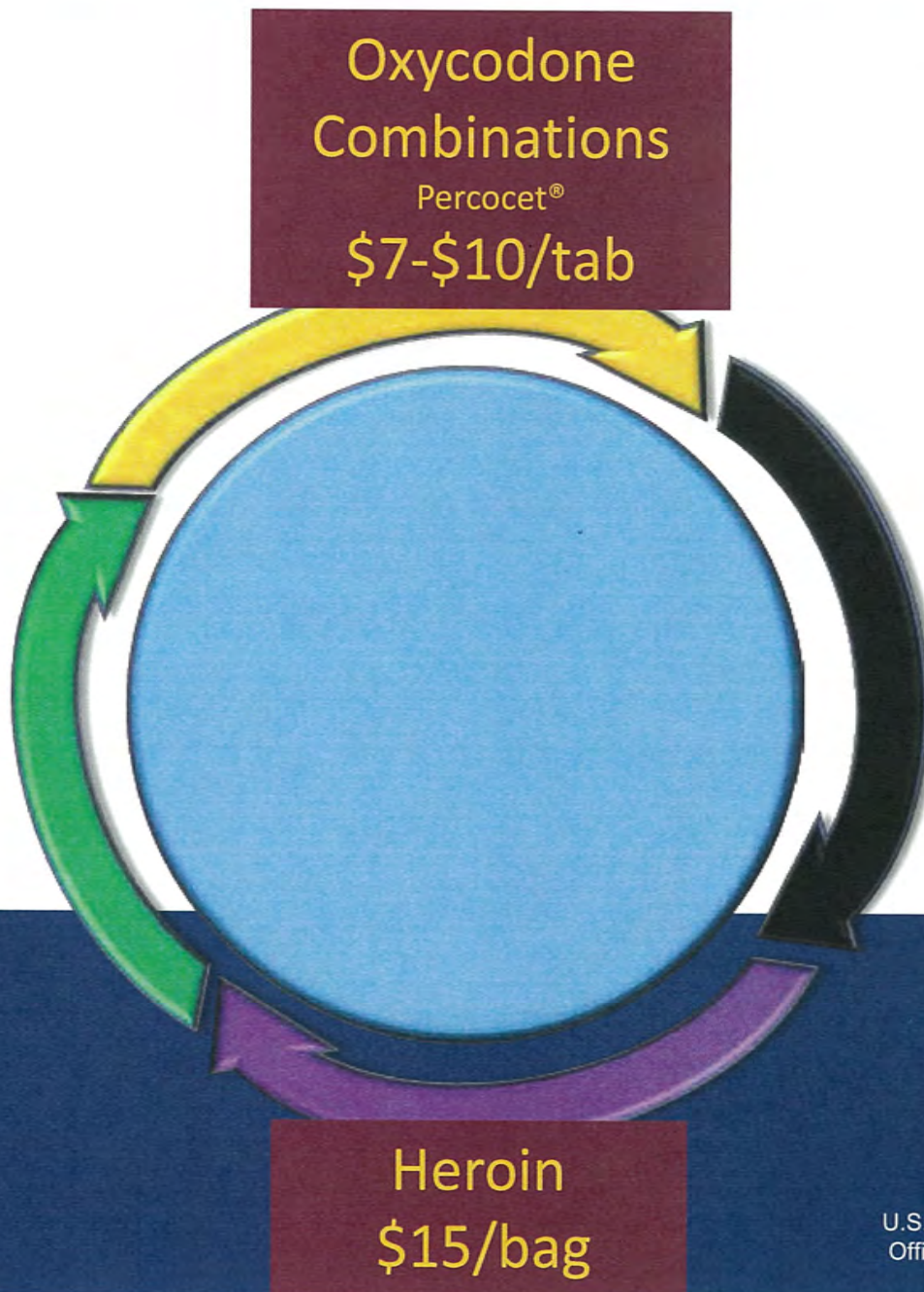


Prescription Opiates v. Heroin

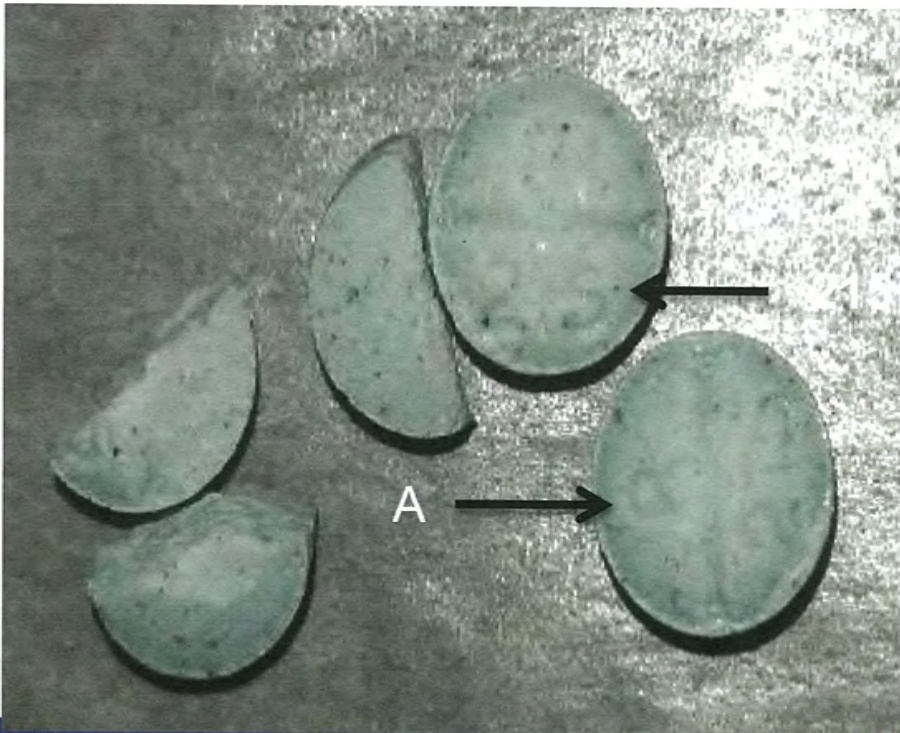


U.S. Drug Enforcement Administration
Office of Diversion Control

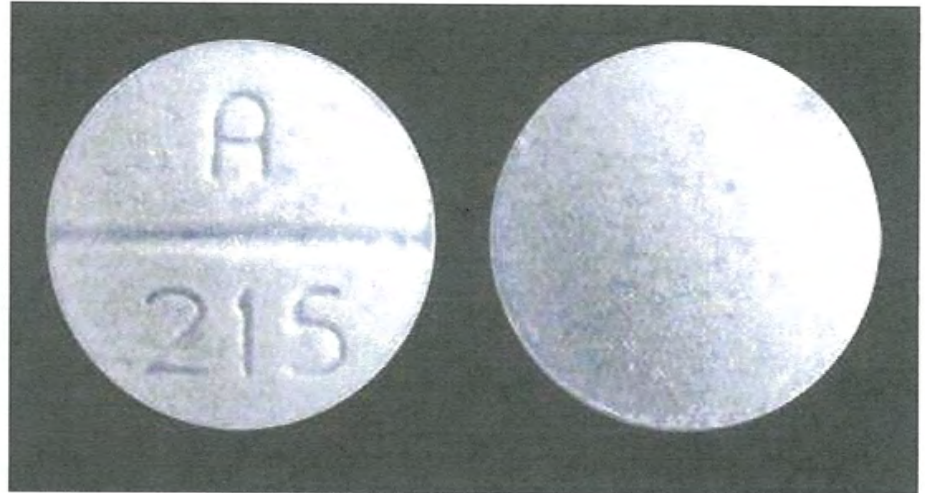
Circle of Addiction & the Next Generation



U.S. Drug Enforcement Administration
Office of Diversion Control



Heroin Seizure



Pharmaceutical Oxycodone 30mg



Non-medical Prescription Opioid Users Who Try Heroin

- Prescription opioid use is a risk factor for heroin use. Approximately 4 out of 5 recent heroin initiates ages 12-49 used prescription opioids non-medically before heroin initiation.¹
- Transition from prescription opioid abuse to heroin use is relatively rare; approximately 4 percent of prescription opioid abuse initiates begin using heroin within five years of their initiation of prescription opioid abuse.²
- Injection-drug users report that tolerance motivates them to try heroin.³
- New research shows that heroin's effects, price, availability, and ease of use motivate heroin users who formerly used prescription opioids.⁴



1. Muhuri, P.K. Gfroerer, J., Davies, C. (2013). Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. SAMHSA CBHSQ Data Review (August).
2. Ibid
3. Lankenau SE, et al. (2012). Initiation into prescription opioid misuse amongst young injection drug users. Int J Drug Policy. 2012 Jan;23(1):37-44. Epub 2011 Jun 20.
4. Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years. JAMA Psychiatry. Published online May 28, 2014. doi:10.1001/jamapsychiatry.2014.366



Criminal Activity



Egregious Activity (Not on the fringes)



United States V. Alvin Yee, M.D.

Dr. Alvin Yee





United States V. Alvin Yee, M.D.

Overview

Dr. Yee primarily met with his “patients” in Starbucks cafes throughout Orange County, California.

He would see up to a dozen patients each night between 7:00 and 11:00 p.m. and wrote these “patients” prescriptions, primarily for opiates, in exchange for cash.

Yee pled guilty to distributing millions of dollars in oxycodone, oxymorphone, hydrocodone, hydromorphone, Adderall® and alprazolam outside the course of professional practice and without a legitimate medical purpose





United States V. Alvin Yee, M.D.

CURES Data (PMP)

During a one-year time period, Yee wrote prescriptions for a total of 876,222 dosage units of all medications combined.

52% of all prescriptions (458,056 dosage units) written by Yee were for oxycodone during the referenced time period.

The top five most commonly abused and diverted prescription drugs – oxycodone, hydrocodone, alprazolam, hydromorphone, and oxymorphone – accounted for 96% of all prescriptions written by Yee.





United States V. Alvin Yee, M.D.

CURES Data (PMP)

Of the oxycodone prescriptions written by Yee, 92% were for the strongest form of immediate release oxycodone available, 30 mg, which is also the highest in demand by both drug abusers and traffickers.

Almost half of Yee's patients were 25 and under.





United States V. Alvin Yee, M.D.

MEDICAL OFFICE
Various Locations, Orange County, California





The Controlled Substances Act: Checks & Balances





Mission

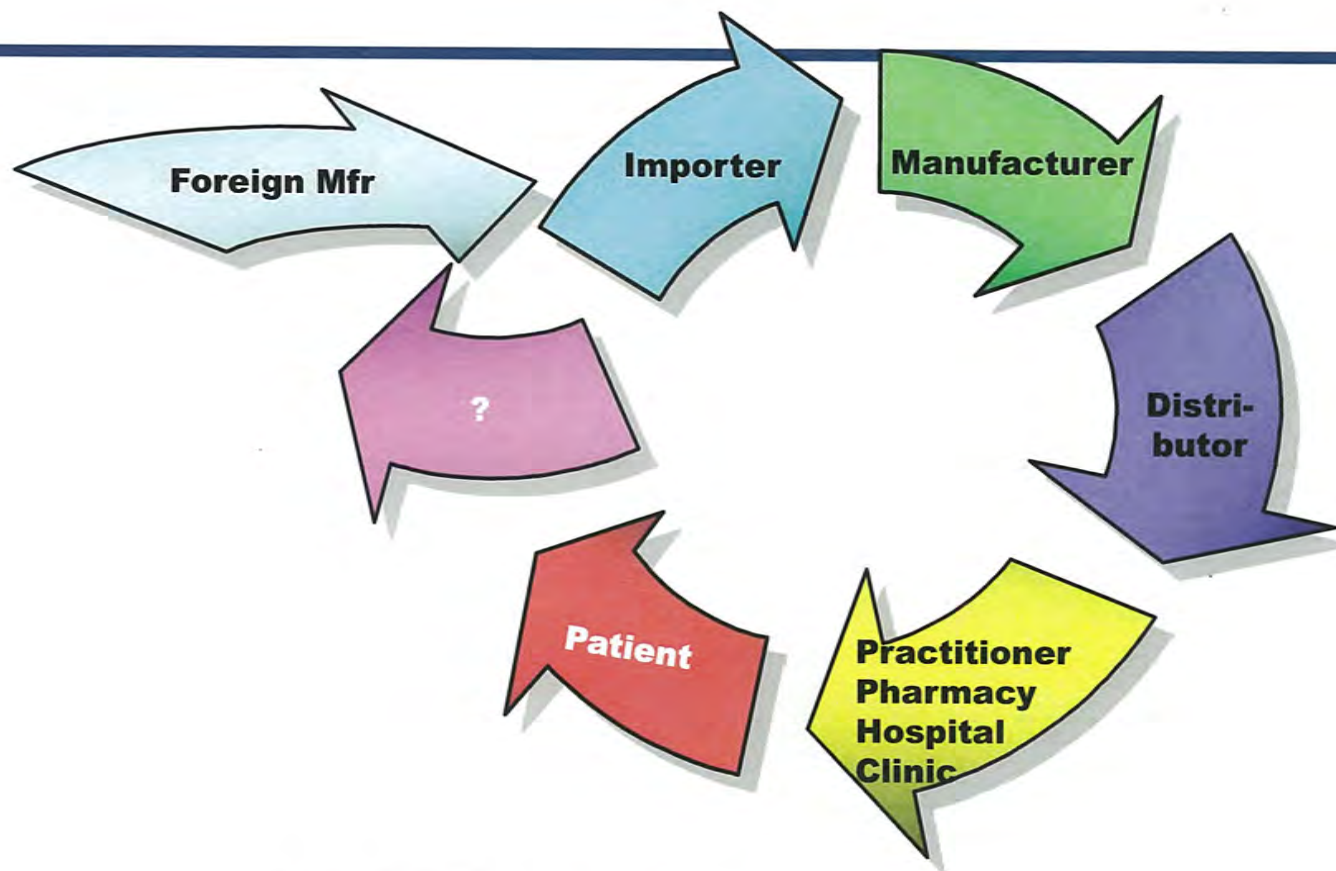
The mission of the Office of Diversion Control is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

while ...

ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs.



Closed System of Distribution

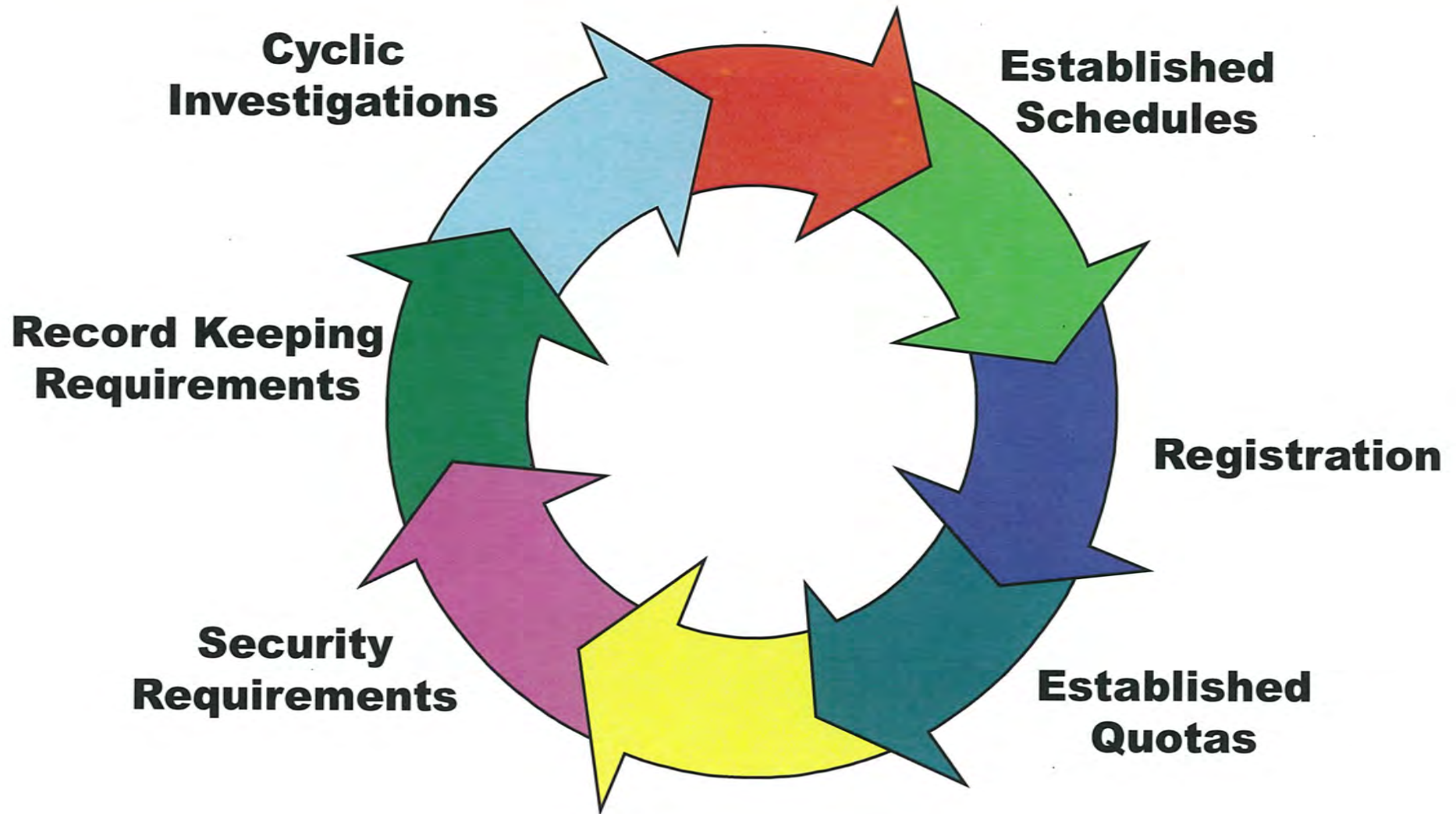


1,604,158 (03/15/2016)

- **Practitioners:** **1,221,972**
- **Retail Pharmacies:** **71,439**
- **Hospital/Clinics:** **16,500**



Closed System of Distribution



Drug Enforcement Administration
Office of Diversion Control



Closed System of Distribution

The DEA is responsible for:

- the oversight of the system
- the integrity of the system
- the protection of the public health and safety



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Legal Obligations: DEA Registrant



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Effective Controls

In order to determine whether a registrant has provided **effective controls** against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for the **physical security controls** and **operating procedures** necessary to **prevent diversion**.

21 CFR § 1301.71(a)



Suspicious Orders

Non-practitioners of controlled substances

“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

21 CFR § 1301.74(b)



Prescriptions

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

21 CFR § 1306.04(a)

United States v Moore 423 US 122 (1975)





Corresponding Responsibility by Pharmacist

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

21 CFR § 1306.04(a)





Corresponding Responsibility by Pharmacist

- A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate.
- When a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription!!!





The Last Line of Defense





Potential Red Flags

Many customers receiving the same combination of prescriptions;
cocktail

Many customers receiving the same strength of controlled substances;
no individualized dosing: multiple prescriptions for the strongest dose

Many customers paying cash for their prescriptions

Early refills

Many customers with the same diagnosis codes written on their
prescriptions;

Individuals driving long distances to visit physicians and/or to fill
prescriptions;



Potential Red Flags continued

- C Customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and
- C Customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).
- O Overwhelming proportion of prescriptions filled by pharmacy are controlled substances
- P Pharmacist did not reach out to other pharmacists to determine why they were not filling a particular doctor's prescription
- V Verification of legitimacy not satisfied by a call to the doctors office



Red Flag?

What happens next?

You attempt to resolve...



Resolution is comprised of many factors

- Verification of a valid practitioner DEA number ! It is not, **however**, the end of the pharmacist's duty. Invalid DEA number = Invalid RX
- Resolution cannot be based solely on patient ID and prescriber verification.
- You must use your professional judgment, training and experience...we all make mistakes
- Knowledge and history with the patient
- Circumstances of prescription presentation
- Experience with the prescribing practitioner
- It does not require a call to the practitioner for every CS RX
- This is not an all-inclusive list...





Who do I call to report a practitioner?


- State Board of Pharmacy, Medicine, Nursing, Dental
- State, County, Local Police
- DEA local office and Tactical Diversion Squad
- Health Department
- HHS OIG if Medicare, Medicaid fraud



www.nabp.net


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 **QUESTIONS? CHAT IS AVAILABLE**

Meet the NABP Executive Committee



The 2015-2016 NABP Executive Committee, including President Edward G. McKinley, MBA, RPh, were inaugurated at the 111th Annual Meeting, [August 2015](#)


2015-2016 Executive Committee



Chairman - Edward G. McKinley, MBA, RPh
President - Edward G. McKinley, MBA, RPh
President-Elect - Michael J. Smith, MBA, RPh

Do You Know What a Doctor Shopper Looks Like?

Americans abuse prescription drugs more than cocaine, heroin, and hallucinogens combined. The "Red Flags" video helps pharmacists identify the warning signs of prescription drug abuse and diversion.





Red Flags for Pharmacists

Verified Pharmacy Program

CPE Monitor

Safe Online Pharmacies

 **NEWSROOM HEADLINES**





The DEA Response





Drug Enforcement Administration

360 Degree Strategy





Drug Enforcement Administration

Community Partnerships



- DEA recognizes we cannot arrest our way out of the drug problem – our goal is lasting success in the communities we serve.
- Education and Prevention are key elements for a true 360 Strategy.
- Law enforcement operations provide an opportunity for community empowerment and a jumping off point for education and prevention efforts.

Prescription Drug Abuse Prevention Plan

- Coordinated effort across the Federal Government
- **Four focus areas:**
 - 1) Education
 - 2) Prescription Drug Monitoring Programs
 - 3) Proper Disposal of Medication
 - 4) Enforcement

EPIDEMIC:
RESPONDING TO AMERICA'S
PRESCRIPTION
DRUG ABUSE CRISIS

2011





DEA Registrant Initiatives

Distributor Initiative

Educate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances

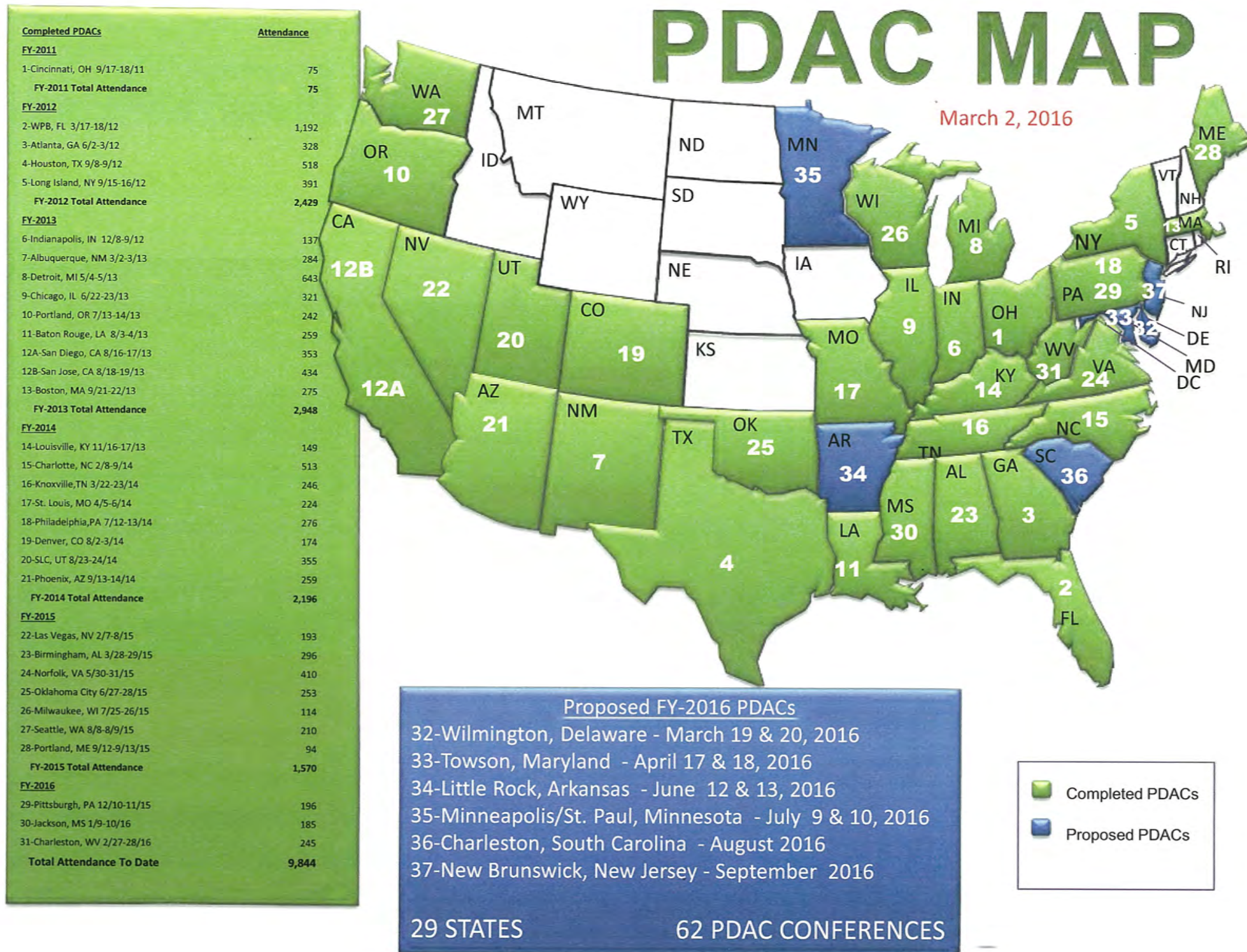
Briefings to **85** firms with **280** registrations



DEA Registrant Initiatives

Pharmacy Diversion Awareness Conference

This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity





DEA Registrant Initiatives

- The Federation of State Medical Boards (FSMB) promotes excellence in medical practice, licensure, and regulation on behalf of 70 state medical and osteopathic Boards across the country in their protection of the public
- DEA and FSMB are currently working on developing strategies to work more effectively and jointly on indiscriminate prescriber investigations in order to facilitate the administrative process to take action against those that are a threat to the public health and welfare quickly, and at the same time not jeopardize a criminal investigation



DEA Registrant Initiatives

“Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances”

- Represents the medical, pharmacist, and supply chain spectrum highlighting the challenges and “red flag” warning signs related to prescribing and dispensing controlled substance prescriptions
- The goal was to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny
- NABP along with 10 national associations and 6 major pharmaceutical firms were the coalition of stakeholders of this document.

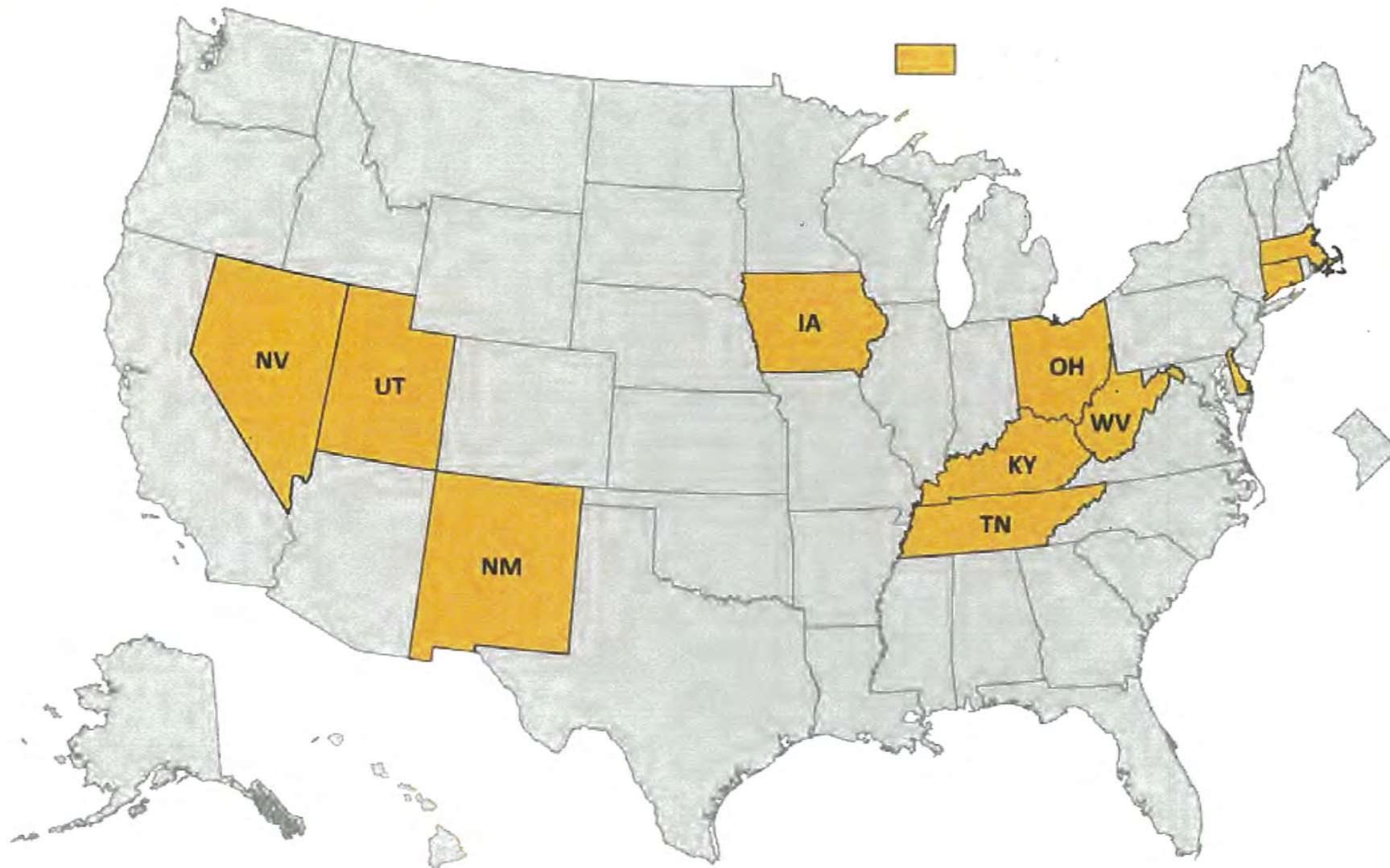


Scheduled Investigations

- Increase in the number of DEA registrants that are required to be investigated to ensure compliance with the Controlled Substances Act and its implementing regulations
- Increase in the frequency of the regulatory investigations
- Verification investigations of customers and suppliers



Since 2011, Eleven States have Passed Legislation Mandating Prescriber Education





CDC Guidelines for Prescribing Opioids for Chronic Pain

- Clinical Reminders:
 - Opioids are not first-line or routine therapy for chronic pain
 - Establish and measure goals for pain and function
 - Discuss benefits and risks and availability of nonopioid therapies with patient



CDC Guidelines for Prescribing Opioids for Chronic Pain (cont'd)

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed



CDC Guidelines for Prescribing Opioids for Chronic Pain (cont'd)

- Evaluate risk factors for opioid-related harms
- Check PDMP for higher dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed



National Take Back Initiative

April 30, 2016

Got Drugs?

Turn in your
unused or expired
medication for safe disposal
Saturday April 30, 2016

Click here
for a collection
site near you.

The poster features a large, 3D-rendered blue pill with the word "dispose" written on it, and a white pill with "unused Rx" written on it. In the background, a faint DEA seal is visible. At the bottom, there are several small logos of participating organizations, including the DEA, the U.S. Department of Justice, and the U.S. Department of Health and Human Services.

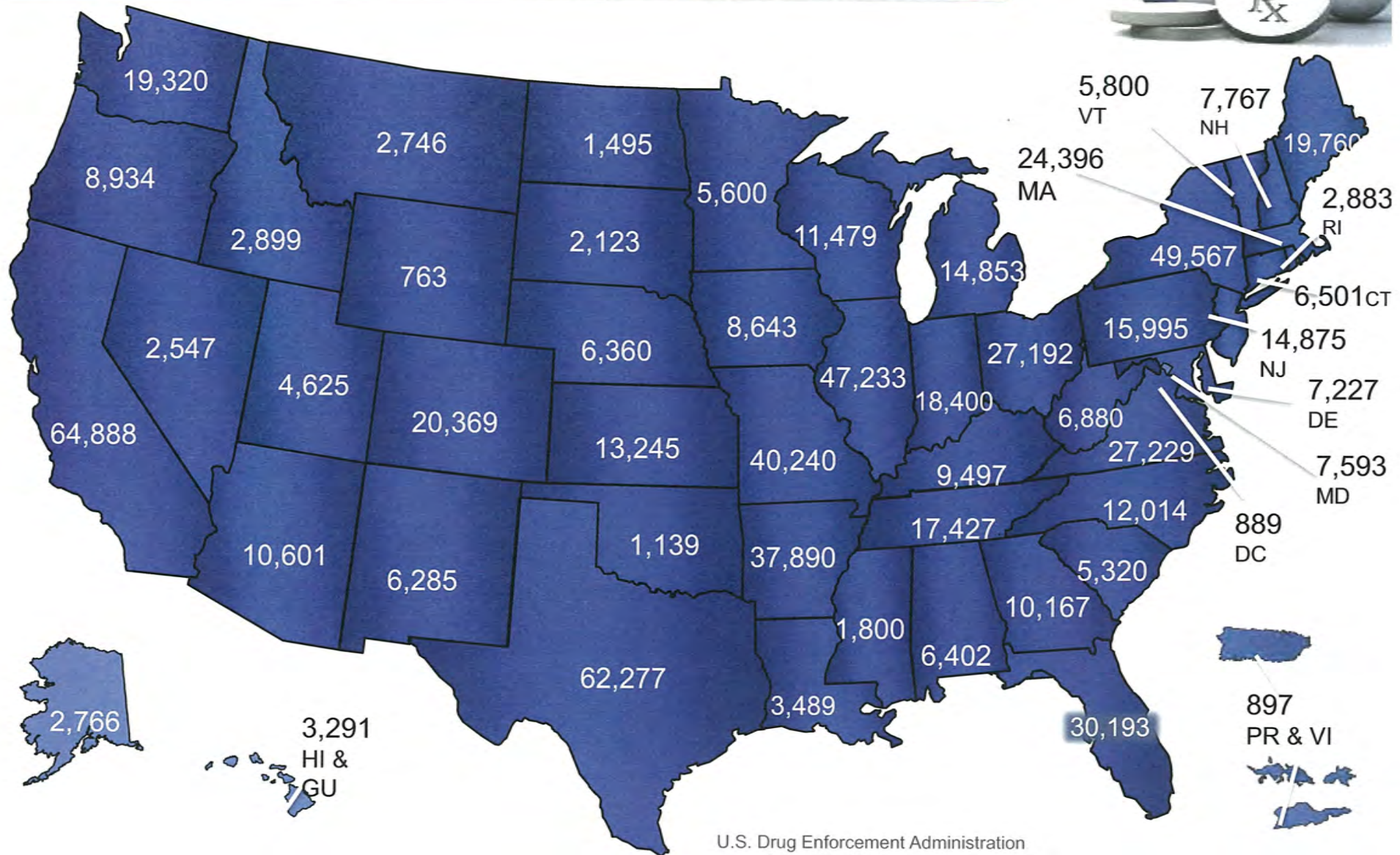
10:00 AM – 2:00 PM

U.S. Drug Enforcement Administration
Office of Diversion Control



10th National Take Back Day: **September 26, 2015**

Total Weight Collected (pounds): 742,771 (371 Tons)



U.S. Drug Enforcement Administration
Office of Diversion Control



Miscellaneous Pharmacy Topics



U.S. Drug Enforcement Administration
Office of Diversion Control



Changes to a Schedule II Prescription

Pharmacist may change:

- Patient's address upon verification
- Dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner.
 - Consultation should be noted on the prescription
 - Must be in compliance with state law/regulation/policy

Pharmacy may not make changes:

- Patient's name
- Controlled substance prescribed (except for generic substitution permitted by state law), or
- Prescriber's signature



Multiple Prescriptions Schedule II Controlled Substances

- Individual practitioner may issue multiple prescriptions which authorizes patient to receive 90-day supply of C-II
 - Each separate prescription is for legitimate medical purpose issued by practitioner acting in usual court of professional practice
 - Written instructions on each prescription indicating earliest date it can be filled
 - Doesn't cause undue risk of diversion by patient
 - Compliance with all other elements of CSA and state laws

21 CFR § 1306.12(b)



Faxed Prescription vs. EPCS

- True electronic prescriptions are transmitted as **electronic data files** to the pharmacy, whose application imports the data file into its database.
- A system that allows the prescriber to “sign” his/her name does **NOT** conform to EPCS regulations.
- A facsimile with a written signature is **NOT** an electronic Rx.

21 CFR § 1306.05(d)





Hospice & LTCF Prescriptions

Schedule II narcotic substances may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile

- Practitioner (or agent) must note it is hospice patient
- Facsimile serves as original written prescription

21 CFR § 1306.11(f), (g) & 1306.13(b)

Schedule III-V prescription

- Written prescription signed by a practitioner, or
- Facsimile of a written, signed prescription transmitted by the practitioner (or agent) to the pharmacy, or
- Oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist



Distribution by Pharmacy to Practitioner

- Practitioner registered to dispense may distribute a quantity of such substance to another practitioner for general dispensing
 - Purchaser must be registered with DEA
 - Schedule III-V - records by purchaser and receiver must conform to 21 CFR § 1304.22(c)
 - Schedule I or II - an order form must be used and must conform to 21 CFR § 1305
 - Total number of controlled substances dispensed cannot exceed 5% of total controlled substances dispensed

21 CFR § 1307.11(a)(1)



Repackaging by Pharmacy

- Practitioner can prepare, compound, package, or label in the course of his professional practice
21 CFR § 1300.01(b)
- Pharmacy can **NOT** repackage drugs (ie 100 ct bottle packaged in smaller size bottles) and sell the drugs in the form of a distribution to any DEA Registrant – including practitioner office.
- Violation of DEA and FDA regulations



Secure and Responsible Drug Disposal Act of 2010



Secure and Responsible Drug Disposal Act of 2010

- ✓ Ultimate users now have more locations where they can securely, safely, responsibly, and conveniently dispose of their unwanted pharmaceutical controlled substances.
- ✓ Expected benefit to the public by:
 - Decreasing the supply of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and
 - Protecting the environment from potentially harmful contaminants by providing alternate means of disposal for ultimate users.





Ultimate User

Ultimate user means as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.”

21 USC § 802(27)

Ultimate user methods of destruction prior to Disposal rule:

- ✓ Disposal in Trash (ONDCP method); or
- ✓ Flushing (FDA opioids and select CSs)
- ✓ National Take-back Event (DEA)
- ✓ Transfer to Law Enforcement
- ✓ (Police Station Receptacles or local Take-back events)
- ✓ DEA



Secure and Responsible Drug Disposal Act of 2010

- CSA amended to provide ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner

21 USC § 822(f) & (g)

- Participation is voluntary

21 USC § 822(g)(2)

- Registrants authorized to collect:

- Manufacturers
- Distributors
- Reverse Distributors
- Narcotic Treatment Programs
- Hospitals/clinics with an on-site pharmacy
- Retail Pharmacies

21 CFR § 1317.40

Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances.



Secure and Responsible Drug Disposal Act of 2010

- Disposal rule eliminated existing 21 CFR § 1307.12 & 1307.21
- New part 1317 contains the requirements on:
 - disposal procedures;
 - registrant inventory
 - collected substances
 - collection of pharmaceutical controlled substances from ultimate users;
 - return and recall; and
 - destruction of controlled substances



Law Enforcement

- Law Enforcement may continue to conduct take-back events.
- Any person may partner with Law Enforcement.
- Law Enforcement shall maintain control and custody of collected substances until secure transfer, storage, or destruction has occurred.
- Authorized collection receptacles and inner liners “should” be used.

21 CFR § 1317.35 and 1317.65





Collection

Drug Enforcement Administration
Office of Diversion Control



Collection

Collection means to receive a controlled substance for the purpose of destruction from an:

- Ultimate user,
- Person lawfully entitled to dispose of an ultimate user decedent's property, or
- LTCF on behalf of an ultimate user who resides or has resided at the facility.

21 USC § 822(g)(3) & (4) and 21 CFR § 1300.01(b)





Design of Collection Receptacles





Design of Collection Receptacles

- Securely fastened to a permanent structure.
- Securely locked, substantially constructed container with permanent outer container and removable inner liner.
- Outer container must have small opening that allows for contents to be added, but does not allow for removal of contents.
- Outer container must display a sign stating only Schedule II-V and non-controlled substances are acceptable substances.
- Schedule I controlled substances are not permitted to be collected



21 CFR § 1317.75(e)

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Office of Diversion Control



Collection Receptacle Inner Liner

- ✓ Waterproof, tamper-evident, and tear-resistant.
- ✓ Removable and sealable upon removal without emptying or touching contents.
- ✓ Contents shall not be viewable from the outside when sealed (i.e., can't be transparent).
- ✓ Size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.).
- ✓ Outside of liner shall have permanent, unique ID number.

21 CFR § 1317.60(a)



Collection Receptacles

- Ultimate users *shall* put the substances directly into the collection receptacle.
- Controlled and non-controlled substances may be comingled.
- Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.
- Registrants **shall not dispose of stock or inventory** in collection receptacles.

21 CFR § 1317.75(b) and (c)



Collection Receptacle Location

- Registered location – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
 - LTCF – located in secure area regularly monitored by LTCF employees.
 - Hospital/clinic – located in an area regularly monitored by employees—not in proximity of where emergency or urgent care is provided.
 - NTP – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

21 CFR § 1317.75(d)



Mail-Back Program

Requirements of mail-back program

- Only lawfully possessed schedules II-V controlled substances may be collected
- Controlled and non-controlled substances may be collected together
- **Must have method of on-site destruction**

21 CFR § 1317.70 (b)



Registrant Disposal

U.S. Drug Enforcement Administration
Office of Diversion Control



Registrant Disposal - Inventory

Practitioner & Non-Practitioner may **dispose of inventory**

- Prompt on-site destruction
- Prompt delivery to **reverse distributor** by **common or contract carrier** or **reverse distributor pick-up**
- Return and recall : Prompt delivery by common or contract carrier or pick-up at the registered location

Practitioner may **also** request assistance from the SAC

Non-practitioner may **also** transport by its own means

21 CFR § 1317.05(a) and (b)



DEA Form 41

- Form 41 shall be used to record the **destruction of all controlled substances, including controlled substances acquired from collectors.**
 - The Form 41 shall include the names and signatures of the **two employees** who witnessed the destruction.
 - Exceptions for DEA Form 41:
 - Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41
 - **Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record need not be maintained on a Form 41**

21 CFR § 1304.21(e)



Abandoned Controlled Substances

- Circumstances when there is no authorized person to dispose of controlled substances
 - School
 - Summer camp
 - Hospital
- Return to ultimate user is not feasible
- Options
 - Contact law enforcement or DEA
 - Destroy on-site

79 FR 53546 (Disposal Final Rule)



Pharmaceutical Wastage

Not subject to **21 CFR Part 1317**

- Destruction does not have to be “non-retrievable”
- DEA Form 41 must not be utilized

- Dispensing must be recorded as a record
21 CFR § 1304.22(c)

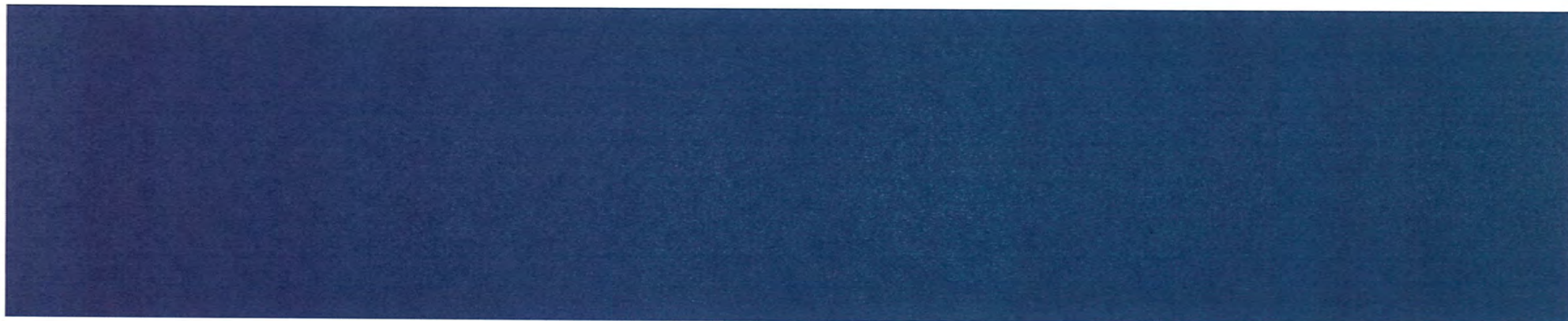
- Clarification memorandum on DEA website at
www.deaDiversion.usdoj.gov



Pharmaceutical Wastage



Questions?





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